Ordinance on Protection against Dangerous Substances and Preparations

(Chemicals Ordinance, ChemO)

of 18 May 2005 (Status as of 1 December 2014)
Please note: this translation does not yet include the amendments of 1.6.2015

The Swiss Federal Council,

based on the Chemicals Act of 15 December 2000 (ChemA)[1],
on Article 26 paragraph 3, Article 29, Articles 30*a*–30*d*, Article 38 paragraph 3, Article 39 paragraph 1, Article 41 paragraph 3, Article 44 paragraphs 2 and 3, Article 46 paragraphs 2 and 3, and Article 48 paragraph 2 of the Federal Act of 7 October 1983 on the Protection of the Environment (EPA)[2],
and on Article 9 paragraph 2 letter c, Article 27 paragraph 2 and Article 48 paragraph 2 of the Waters Protection Act of 24 January 1991[3],
and in implementation of the Federal Act of 6 October 1995[4] on Technical Barriers to Trade,[5]

ordains:

Title 1: General Provisions

Art. 1 Aim and scope

[1] This Ordinance regulates:

a. the determination and assessment of dangers and risks that substances and preparations may pose to human life and health and to the environment;

b. the conditions under which substances and preparations that may endanger people or the environment are placed on the market;

c. the handling of substances and preparations that may endanger people or the environment;

AS **2005** 2721
1 SR **813.1**
2 SR **814.01**
3 SR **814.20**
4 SR **946.51**
5 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

d. the way in which data relating to substances and preparations is processed by the enforcement authorities.

[2] This Ordinance applies to biocidal products and plant protection products insofar as they are referred to in the Ordinance of 18 May 2005[6] on Biocidal Products or the Ordinance of 18 May 2005[7] on Plant Protection Products.

[3] This Ordinance applies to radioactive substances and preparations, excluding effects attributable to the radioactive nature of these substances and preparations.

[4] Only Articles 7–10, 13–15 and 95 apply to cosmetic products[8] and only with regard to environmental protection and classification or evaluation in relation to risks to the environment.

[5] This Ordinance does not apply to:

a. the transport of substances and preparations by road, rail, water, air or pipelines;

b.[9] the transit of substances and preparations under customs supervision, provided that this does not involve any processing or transformation;

c. substances and preparations in the form of finished products ready for supply to the final user that fall into the following categories:

1. foodstuffs as defined by Article 3 of the Foodstuffs Act of 9 October 1992[10],

2. medicinal products as defined by Article 4 paragraph 1 letter a and medical devices as defined by Article 4 paragraph 1 letter b of the Therapeutic Products Act of 15 December 2000[11],

3. animal feedingstuffs as defined by Article 3 paragraph 1 of the Feedstuffs Ordinance of 26 May 1999[12];

d. weapons as defined by Article 4 paragraph 1 and ammunition as defined by Article 4 paragraph 4[13] of the Weapons Act of 20 June 1997[14];

e. substances, preparations and objects which are waste according to Article 7 paragraph 6 of the EPA.

6 SR **813.12**
7 [AS **2005** 3035 4097 5211, **2006** 4851, **2007** 821 No III 1469 Annex 4 No 54 1843 4541 6291, **2008** 2155 4377 Annex 5 No 11 5271, **2009** 401 Annex No 3 2845, **2010** 2101. AS **2010** 2331 Art. 84]. See today: the Ordinance of 12 May 2010 (SR **916.161**).
8 Expression in accordance with No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821). This change has been made throughout the text.
9 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
10 SR **817.0**
11 SR **812.21**
12 [AS **1999** 1780 2748 Annex 5 No 6, **2001** 3294 No II 14, **2002** 4065, **2003** 4927, **2005** 973 2695 No II 19 5555, **2007** 4477 No IV 70, **2008** 3655 4377 Annex 5 No 14, **2009** 2599, **2011** 2405. AS **2011** 5409 Art. 77]. See today: the Ordinance of 26 Oct. 2011 (SR **916.307**).
13 Now: Art. 4 para. 5.
14 SR **514.54**

[6] Only Article 49 applies to dangerous substances and preparations that are imported, relabelled and then exported.[15]

Art. 2 Definitions

[1] By way of clarification of the definitions given in the Chemicals Act, in this Ordinance:

a.[16] *substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

b.[17] …

c.[18] *manufacturer* means

1. any natural or legal person domiciled in Switzerland or with a registered office or branch in Switzerland, who manufactures, extracts or imports substances, preparations or objects in a professional or commercial capacity.
2. Also deemed to be a manufacturer is any person who obtains substances, preparations or objects in Switzerland and supplies them on a commercial basis, without altering their composition:
   – under his own name, without specifying the name of the original manufacturer,
   – under his own trade name,
   – in packaging other than that intended by the original manufacturer, or
   – for some other purpose.
3. If a person arranges for the manufacture of a substance, preparation or object in Switzerland by a third party, this person is deemed to be the sole manufacturer if he is domiciled or has a registered office or branch in Switzerland.

[2] In addition, in this Ordinance:

a.[19] *object* means an article, consisting of one or more substances or preparations, which during production is given a special shape, surface or design

15 Inserted by No I of the Ordinance of 28 Feb. 2007 (AS **2007** 821). Amended by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
16 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
17 Repealed by No I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
18 Amended by No I of the Ordinance of 28 February 2007, in force since 1 April 2007 (AS **2007** 821).
19 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1. Feb. 2009 (AS **2009** 401).

which determines its end use function to a greater degree than does its chemical composition;

b.[20] *existing substance* means any substance listed in EINECS[21] of 15 June 1990[22];

c. *polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising:

1. a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and

2.[23] less than a simple weight majority of molecules of the same molecular weight; these molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units;

c[bis].[24] *monomer* means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

c[ter].[25] *monomer unit* means the reacted form of a monomer substance in a polymer;

d.[26] *intermediate* means a substance manufactured and used solely for chemical processing during which it is transformed into one or more other substances;

e. *secondary product* means any substance formed by chemical or biochemical transformation during the storage, use or disposal of a substance or preparation;

f.[27] …

g. *sole representative* means any natural or legal person that is authorised by a manufacturer whose domicile or registered office is located abroad to notify a substance in Switzerland and represents several importers designated by that manufacturer;

20 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
21 European Inventory of Existing Commercial Chemical Substances.
22 OJ C 146 A of 15.6.1990, p.1, corrected in OJ C 54 of 1.3.2002, p. 13). The EINECS inventory can be consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; it can also be accessed on the Internet at http://esis.jrc.ec.europa.eu/index.php?PGM=ein.
23 Amended by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
24 Inserted by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
25 Inserted by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
26 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
27 Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).

h.[28] *scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions and involving quantities of less than 1 tonne per year;

i.[29] *product and process-orientated research and development* means any scientific development related to product development or the further development of a substance on its own, in preparations or in objects in the course of which pilot plant or production trials are used to define the production process or test the fields of application of the substance;

j.[30] *robust study summary* means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study, minimising the need to consult the full study report;

k.[31] *exposure scenario* means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer controls, or recommends customers to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

l.[32] *hazard class* means the nature of the physical, health or environmental hazard;

m.[33] *nanomaterial* means a material containing particles in an unbound state or as an aggregate or as an agglomerate, where one or more external dimensions is in the size range 1–100 nm, or a material where the specific surface area by volume is greater than 60 m^2/cm^3. A material is only considered to be a nanomaterial if it is deliberately produced to utilise the properties arising from the defined external dimensions of the particles it contains, or from the defined surface area by volume of the material. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm are considered to be nanomaterials.

[3] Any other terms which are used in various senses in the legislation underlying this Ordinance are used here as defined in the Chemicals Act.

28 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
29 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
30 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
31 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
32 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
33 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

4 For the correct interpretation of Regulation (EC) No 1907/2006 (REACH Regulation)[34] and Regulation (EC) No 1272/2008 (CLP Regulation)[35], to which reference is made in this Ordinance, the correspondences specified in Annex 5 apply.[36]

Art. 3[37] Dangerous substances and preparations

The following are dangerous:

a. substances which fulfil the criteria relating to physical hazards, health hazards, environmental hazards or other hazards specified in Parts 2–5 of Annex I to the CLP Regulation[38];

b. preparations which:

1. are classified exclusively in accordance with Article 10 paragraph 1 and have one of the properties referred to in Articles 4–6 and described in detail in Sections 2–5 of Annex VI to Directive 67/548/EEC[39],

2. are classified in accordance with Article 10 paragraph 2 and fulfil the criteria relating to physical hazards, health hazards, environmental hazards or other hazards specified in Parts 2–5 of Annex I to the CLP Regulation.

Art. 4 Hazardous physicochemical properties

Preparations which have one of the following properties are deemed to have hazardous physicochemical properties:[40]

a. *explosive*: if they may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

34 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1; last amended by Regulation (EU) No 253/2011, OJ L 69, 16.3.2011, p. 7.

35 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1; last amended by Regulation (EC) No 286/2011, OJ L 83, 30.3.2011, p. 1.

36 Inserted by No. I of the Ordinance of 14 Jan. 2009 (AS **2009** 401). Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

37 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

38 See footnote to Art. 2 para. 4.

39 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 196, 16.8.1967, p. 1; Last amended by Regulation (EC) No 1272/2008, OJ L 353, 31.12.2008, p. 1.

40 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

b. *oxidising*: if they give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

c. *extremely flammable*: if they have an extremely low flash-point and a low boiling point or, as gases, are flammable in contact with air at ambient temperature and pressure;

d. *highly flammable*:[41] if they:

1. may become hot and finally catch fire in contact with air at ambient temperature without any application of energy,
2. in a solid state, may readily catch fire after brief contact with a source of ignition and continue to burn or to be consumed after removal of the source of ignition,
3. have a very low flash-point, or
4. in contact with water or damp air, evolve extremely flammable gases in dangerous quantities;

e. *flammable*: if they have a low flash-point.

Art. 5 Properties dangerous to health

Preparations which have one of the following properties are deemed to have properties dangerous to health:[42]

a. *very toxic*: if they cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin in very low quantities;

b. *toxic*: if they cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin in low quantities;

c. *harmful*: if they can cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

d. *corrosive*: if they can, on contact with living tissues, destroy them;

e. *irritant*: if, without being corrosive, they can cause inflammation through immediate, prolonged or repeated contact with the skin or mucous membrane;

f.[43] *sensitising*: if they can elicit a reaction of hypersensitisation following inhalation or skin contact such that on further exposure to the preparation characteristic adverse effects are produced;

g. *carcinogenic*: if they can induce cancer or increase its incidence if they are inhaled or ingested or if they penetrate the skin;

41 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821). This change has been made throughout the text.
42 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
43 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

h. *mutagenic*: if they can induce heritable genetic defects or increase their incidence if they are inhaled or ingested or if they penetrate the skin;

i. *toxic for reproduction*: if they can produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity if they are inhaled or ingested or if they penetrate the skin.

Art. 6[44] Properties dangerous to the environment

Preparations which, were they to enter the environment, would or could present an immediate or delayed danger for one or more components of the environment are deemed to have properties dangerous to the environment.

Art. 6*a*[45] Persistence, bioaccumulation and toxicity

1. Substances are considered *persistent, bioaccumulative and toxic (PBT)* if they fulfil the criteria defined in Sections 1.1.1–1.1.3 of Annex XIII to the REACH Regulation[46].

2. Substances are considered *very persistent and very bioaccumulative (vPvB)* if they fulfil the criteria defined in Sections 1.2.1 and 1.2.2 of Annex XIII to the REACH Regulation.

Title 2: Marketing Requirements

Chapter 1: Self-Regulation

Section 1: Fundamental Obligations

Art. 7 General provisions[47]

[1] The self-regulation system introduced by Article 5 of the Chemicals Act and Article 26 of the EPA requires manufacturers to assess whether substances or preparations may endanger human life or health or the environment. In accordance with this Ordinance, manufacturers must:

a. classify;

b. package and;

c. label substances and preparations;

d. prepare exposure scenarios and;

44 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

45 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401). Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

46 See footnote to Art. 2 para. 4.

47 Inserted by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223)

e. compile safety data sheets.[48]

[1bis] and [1ter] …[49]

[2] In the case of objects containing dangerous substances, substances rated as PBT or vPvB, or substances listed in Annex 7, self-regulation under Article 26 of the EPA requires manufacturers to assess whether these substances may endanger the environment or indirectly endanger human health when these objects are used as intended, or in a foreseeable manner, or when they are appropriately disposed of.[50]

[2bis] In the case of objects containing substances listed in Annex 7, manufacturers must assess whether these substances may endanger human health when these objects are used as intended, or in a foreseeable manner, or when they are appropriately disposed of.[51]

[3] Manufacturers must collect all available data of relevance to the obligations referred to in paragraphs 1 and 2.

[4] Any person importing substances, preparations or objects with dangerous constituents in a professional or commercial capacity must comply with the obligations listed under paragraphs 1 and 2 before supplying them to a third party for the first time or, if they are for the importer's own use, before using them for the first time.

Art. 7*a*[52]

Section 2: Classification of Substances

Art. 8[53] Classification by the manufacturer

[1] Manufacturers must classify substances in accordance with the following provisions.

a. Articles 5–15 of the CLP Regulation[54];

b. Article 4 paragraph 3 of the CLP Regulation, if the Federal Department of Home Affairs (FDHA) has prescribed an official classification in accordance with Article 9; this will be based on Table 3.1 of Part 3 of Annex VI to the CLP Regulation.

48 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
49 Inserted by No I of the Ordinance of 14 Jan. 2009 (AS **2009** 401). Repealed by No I of the Ordinance of 10 Nov. 2010, with effect from 1 Dec. 2010 (AS **2010** 5223).
50 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103)
51 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
52 Inserted by No. I of the Ordinance of 10. Nov. 2010 (AS **2010** 5223). Due to the repeal of Art. 56*c*-56*e* on 1 Dec. 2012 no longer relevant. A new version will come into force at a later date.
53 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
54 See footnote to Art. 2 para. 4.

2 Manufacturers obliged to compile a safety data sheet in accordance with Article 52 must additionally classify substances in accordance with:

a. the criteria defined in Annex VI to Directive 67/548/EEC[55];

b. Article 4 paragraph 3 of the CLP Regulation, if the FDHA has prescribed an official classification in accordance with Article 9; this will be based on Table 3.2 of Part 3 of Annex VI to the CLP Regulation.

3 Classification must be based:

a. in the case of existing substances: on data collected in accordance with Article 7 paragraph 3;

b. in the case of new substances: on data in the technical dossier as specified in Article 18 paragraph 2 letter b.

Art. 9 Official classification

1 The Federal Department of Home Affairs (FDHA) may prescribe the classification and resultant labelling for certain substances with the agreement of the Federal Department of the Environment, Transport, Energy and Communications (DETEC) and the Federal Department of Economic Affairs, Education and Research (EAER)[56]. It may declare European classifications to be applicable.

2 The Federal Office of Public Health (FOPH) may, with the agreement of the Federal Office for the Environment (FOEN)[57] and the State Secretariat for Economic Affairs (SECO), update the list of European classifications declared to be applicable.

Section 3: Classification of Preparations

Art. 10[58] Principle

1 Manufacturers of preparations must classify these in accordance with Articles 11–15.

2 In addition to paragraph 1, they may classify preparations in accordance with the following provisions:

a. Articles 5–15 of the CLP Regulation[59]; or

b. Annex VII to the CLP Regulation.

55 See footnote to Art. 3 let. b.
56 The designation of this unit of the Federal Administration was Amended by Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**). This amendment has been made throughout the text.
57 The designation of this unit of the Federal Administration was Amended by Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**). This amendment has been made throughout the text.
58 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
59 See footnote to Art. 2 para. 4.

Art. 11 Classification with regard to hazardous physical and chemical properties

[1] Manufacturers of preparations must classify them with regard to hazardous physicochemical properties on the basis of the criteria laid down in Chapter 2 of Annex VI to Directive 67/548/EEC.

[2] The flammability and oxidising properties of gaseous preparations must be evaluated in accordance with Section 9.1.1 of Annex VI to Directive 67/548/EEC.

[3] If the composition of a preparation is altered, there is no obligation to determine the physicochemical properties of the altered preparation if it can be assumed, on the basis of the current state of scientific knowledge, that these properties would not lead to any change in the classification.

[4] Manufacturers are not required to classify preparations with regard to hazardous physicochemical properties if:

a. the preparation is made up exclusively of substances not classified as explosive, oxidising, extremely flammable, highly flammable or flammable; and

b. the preparation itself is highly unlikely to have any of the properties listed in a above.

Art. 12 Classification with regard to properties dangerous to health

[1] Manufacturers of preparations must classify them with regard to properties dangerous to health using the calculation method described in Annex II to Directive 1999/45/EC[60].[61]

[2] Classification may also be based on test results, provided that:

a. it does not relate to carcinogenic, mutagenic or reproductive toxicity properties;

b. it can be demonstrated that the calculation method referred to in paragraph 1 is not appropriate for classifying the preparation; or

c. available results of animal tests do not permit correct classification.

[3] Classification based on test results must be established in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

[4] If a preparation has been classified both by the calculation method and on the basis of test results, the classification based on test results takes precedence.

[5] Where it can be demonstrated that the dangerous effects of a preparation on human health differ from the effects underlying the classification as specified in paragraphs

60 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200 of 30.7.1999, p. 1; last amended by Regulation (EC) No 1272/2008, OJ L 353 of 31.12.2008, p. 1. This text can be accessed on the Internet at www.cheminfo.ch.

61 Amended by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).

1 and 3, this preparation must be classified according to its effects on human health. The demonstration must involve:

a. epidemiological studies;

b. scientifically valid case studies as specified in Annex VI to Directive 67/548/EEC; or

c. statistically backed experience from Switzerland or abroad, such as the assessment of data from poison information units or concerning occupational diseases.

[6] If, when a preparation is classified using the calculation method referred to in paragraph 1, it is demonstrated that the properties dangerous to health would be overestimated or underestimated because of interactions between the substances present in the preparation, these interactions must be taken into account in the classification.

Art. 13 Classification with regard to properties dangerous to the environment

[1] Manufacturers of preparations must classify them with regard to their properties dangerous to the environment:

a. using the calculation method described in Annex III to Directive 1999/45/EC; or

b. on the basis of test results as defined in Article 34, using the criteria laid down in Annex VI to Directive 67/548/EEC.

[2] If a preparation has been classified both by the calculation method and on the basis of test results, the classification based on test results takes precedence.

Art. 14 Concentrations requiring substances to be taken into consideration

If a preparation is classified using the calculation method, only those constituents dangerous to health or dangerous to the environment that are present in concentrations above the thresholds laid down in Article 3 paragraph 3 of Directive 1999/45/EC need be taken into consideration.

Art. 15 Re-evaluation with regard to properties dangerous to health or the environment

[1] Manufacturers of preparations must re-evaluate them when they:

a. replace or add a constituent; or

b. alter the composition of a preparation, thereby producing the following changes in initial concentrations:

1. in the case of constituents dangerous to health: as specified in Article 6 number 4 first indent of Directive 1999/45/EC,

2. in the case of constituents dangerous to the environment: as specified in Article 7 number 3 first indent of Directive 1999/45/EC.

[2] Re-evaluation is not required when it can be scientifically demonstrated that it would not result in any change to the initial classification.

Chapter 2: Notification of New Substances and Declaration of New Substances not subject to Notification Requirements

Section 1: Notification of New Substances

Art. 16[62] Obligation to notify

[1] Manufacturers of a new substance or their sole representative must notify the new substance to the Notification Authority before placing it on the market for the first time either alone or within a preparation or object from which it may be released under normal or reasonably foreseeable conditions of use.

[1bis] If a new substance is contained in a polymer as a monomer or as another substance in the form of monomer units or chemically bound, paragraph 1 applies for the substance as such.[63]

[2] The Notification Authority may require the notification of a substance contained in an object if it has reason to believe that the substance may be released when the object is used.

Art. 16*a*[64] Relevant quantity of a substance

The relevant substance quantities mentioned in Articles 17, 18, 18*b*, 22, 25, 59, and 60 and in Annex 3 are determined by the following criteria:[65]

a. if the substance is manufactured within the European Economic Area (EEA): the total quantity manufactured annually in the EEA by a manufacturer, of which a part is supplied to the notifier;

b. if the substance is manufactured in Switzerland, the larger of the following quantities:
   1. the annual quantity placed on the market in Switzerland, or
   2. the largest quantity exported annually to a specific European importer in the EEA;

c. if the substance is manufactured outside Switzerland and the EEA and the notifier imports the substance directly from the country of manufacture: the annual quantity imported into Switzerland;

62 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
63 Inserted by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
64 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
65 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

d. if the substance is manufactured outside Switzerland and the EEA and the notifier imports the substance from an EEA member state: the total quantity imported into the EEA annually by an importer, of which a part is supplied to the notifier.

Art. 17[66] Exemptions from the obligation to notify

[1] Notification is not required for:

a.[67] polymers or substances contained in polymers in a concentration of less than two per cent by weight;

b. substances that appear on the No-Longer Polymer List[68];

c. substances for which the relevant quantity in accordance with Article 16*a* is less than 1 tonne per year;

c[bis].[69] substances placed on the market in quantities less than 1 tonne per year, if they are used exclusively for scientific research and development;

d. substances placed on the market by a manufacturer:
   1. purely for product and process-orientated research and development purposes,
   2. limited to the quantities required for the said purposes and
   3. for a period not exceeding five years; upon justified request, the Notification Authority may in consultation with the assessment authorities extend this period by an additional five or ten years;

e. substances used exclusively as raw materials, active ingredients or additives in foodstuffs, therapeutic products and animal feedingstuffs;

f. substances obtained in Switzerland;

g.[70] intermediates, provided that they are not monomers;

h.[71] substances listed in Annex V to the REACH Regulation[72].

66 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
67 Amended by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
68 Notification of New Substances in accordance with Directive 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances. No-Longer Polymer List Version 3 (EUR 20853 EN/3) 2007. The list can be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern; it can also be accessed on the Internet at www.cheminfo.ch
69 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
70 Amended by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
71 Inserted by No I of the Ordinance of 10 Nov. 2010 (AS **2010** 5223). Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
72 See footnote to Art. 2 para. 4.

[2] If there are reasons to suppose that a given substance that is exempt from notification under paragraph 1 may endanger people or the environment, the Notification Authority shall require the manufacturer to present certain test reports when so requested by an assessment authority. The requirements specified for these test reports must not go beyond those for the technical dossier referred to in Annex 3 number 7 letter a, number 8 letter a and number 9 letter a.

Art. 18[73] Form and content of the notification

[1] The notification must be submitted in quadruplicate. The accompanying letter must be written in an official language and submitted on paper. The information and documents may be written in English instead of in an official language and may be submitted on electronic media instead of on paper.

[2] The notification must contain the following information and documents:

a. the decisive substance quantity in accordance with Article 16*a* together with an indication of which of the requirements (Art. 16*a* let. a, b, c or d) applies;

b. a technical dossier with the following information specified in Annex 3:
   1. the identity of the notifier,
   2. the identity of the substance,
   3. information on manufacture and use,
   4. classification and labelling,
   5. guidelines for safe use,
   6. if applicable, an exposure assessment,
   7. robust study summaries with regard to the physical and chemical properties,
   8. robust study summaries with regard to the properties dangerous to health,
   9. robust study summaries with regard to the properties dangerous to the environment.

c. if the relevant substance quantity in accordance with Article 16*a* amounts to 10 tonnes per year or more: a chemical safety report in accordance with Article 18*a*;

d. a proposed safety data sheet in the case of dangerous substances or PBT or vPvB substances;

e. all available documents and information on exposure and the substance's harmful effects on people and the environment, unless these are already apparent from the technical dossier described under letter b;

[3] Paragraph 2 letter c does not apply to new substances that are placed on the market in the form of preparations if the concentration of the substance is lower than the following levels:

73 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

a. the concentration limits described in Part B of Annex II or Part B of Annex III to Directive 1999/45/EC;

b. the concentration limits established during the official classification (Art. 9);

c. the applicable concentrations established in Article 3 paragraph 3 of Directive 1999/45/EC; or

d. 0.1 % by weight for PBT or vPvB substances.

4 If in the situations listed in Article 16*a* letter a or d, certain documents specified in paragraph 2 are not available, or if the notifier cannot reasonably be expected to obtain them, the notifier must provide corresponding proof.

5 The Notification Authority may request that the notifier provide test reports that exceed the scope of the technical dossier and that are relevant to the assessment of the substance, provided they are available and the notifier can reasonably be expected to obtain them.

Art. 18*a*[74] Chemical safety reports

The chemical safety report contains the chemical safety assessment in accordance with Annex I to the REACH Regulation[75]. A chemical safety assessment includes the following steps:[76]

a. a human health hazard assessment;

b. a physicochemical hazard assessment;

c. an environmental hazard assessment;

d. PBT and vPvB assessment;

e.[77] if the substance fulfils the criteria specified in Article 14 paragraph 4 of the REACH Regulation:

1. an exposure assessment covering all identified uses,
2. a description of the risks associated with all identified uses.

Art. 18*b*[78] Substances for which a notification has been submitted in the EU prior to 1 June 2008

1 For substances notified in the EU prior to 1 June 2008, the documents specified in Article 18 paragraph 2 numbers 2–9 may be replaced by the notification submitted in the EU and any updated information together with the corresponding notification number and the risk assessment, if available.

74 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
75 See footnote to Art. 2 para. 4.
76 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
77 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
78 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

2 If the decisive substance quantity in accordance with Article 16*a* exceeds the quantity threshold for which the substance has been notified in the EU, the notification must contain the updated information in accordance with Article 18 paragraph 2 that corresponds to the higher quantity threshold.

3 When a new substance is notified for the first time, the Notification Authority may, in consultation with the assessment authorities, accept a summary of the technical dossier if the notifier demonstrates that:

a. the data protection period in the EU has expired; and

b. the identity of the substance and the content and identity of the impurities are identical to those for the substance notified in the EU.

Art. 19[79]

Section 2: Use of Data from Previous Notifiers and Data Protection Period

Art. 20 Use of data from previous notifiers

1 The Notification Authority may refer to data from a previous notifier instead of data produced by the notifier if:

a. the new notifier proves with a letter of access from a previous notifier that the latter agrees to the Notification Authority consulting its data; or

b. the data protection period has expired.

2 The notifier must not refer to data from previous notifiers regarding:

a. the identity and purity of the substance and the nature of any impurities;

b. action to render the substance harmless.

3 The rules of competition law and intellectual property are not affected by the provisions of this section.

Art. 21 Data protection period

1 The data protection period is 10 years.

2 For data which must be submitted subsequently in accordance with Article 60, the protection period is 5 years. If the data protection period laid down in paragraph 1 has not yet expired, the protection period for data submitted subsequently is extended accordingly.

79 Repealed by No I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).

Art. 22 Mandatory advance enquiries to avoid tests on vertebrates

[1] Anyone planning tests on vertebrates for notification purposes must contact the Notification Authority in writing to enquire whether data from such tests is already available (Art. 12 of the Chemicals Act).

[2] This enquiry must contain information on:

a. the identity of the substance in accordance with Article 18 paragraph 2 letter b number 2;

b. the decisive substance quantity of the substance in accordance with Article 16*a*.[80]

Art. 23 Use of data from previous tests with vertebrates

[1] If the Notification Authority already has adequate data from previous tests with vertebrates, it shall inform the notifier of the extent to which further tests on vertebrates are unnecessary for the purposes of the notification.

[2] If the data is derived from vertebrate tests of previous notifiers and if the protection period for this data has not yet expired, the Notification Authority shall proceed as follows:

a. It shall provide the previous notifiers with information on:
   1. which parts of their data it intends to use for the benefit of the new notifier,
   2. the address of the new notifier;

b. It shall inform the new notifier of the addresses of the previous notifiers.

[3] Within 30 days, the previous notifiers may object to the immediate use of their data and apply for a delay in the use of the data.

[4] If no application for a delay is received, the Notification Authority shall order the use of the data.

[5] If an application for a delay is received, the Notification Authority shall order:

a. which parts of the data of the previous notifiers are to be used,

b. that notification of the substance is to be delayed by the period which would be required by the notifier to supply his own data.

[6] At the request of the new notifier, the Notification Authority shall draw up summaries of the data used; this does not prejudice the provisions on confidential data specified in Article 85.

80 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Art. 24 Previous notifiers' entitlement to remuneration for data from tests on vertebrates

[1] The previous notifiers shall be entitled to fair remuneration from the new notifier for the use of their data from tests on vertebrates protected in accordance with Article 21.

[2] If the notifiers cannot reach agreement on remuneration within 6 months, the Notification Authority, at the request of one notifier, shall decide on the amount of the remuneration, taking the following factors in particular into account:

a. the costs incurred in obtaining the test results;

b. the remaining period of protection for the data concerned;

c. the number of entitled notifiers.

[3] The previous notifiers may request the Notification Authority to prohibit the placing of the substance on the market until the new notifier has paid them the remuneration.

Section 3: Declaration of New Substances for Product and Process-orientated Research and Development[81]

Art. 25[82] Obligation to make a declaration

If the relevant substance quantity in accordance with Article 16*a* is 1 tonne per year or more and if the new substance is exempt from notification under Article 17 paragraph 1 letter d, the manufacturer or the manufacturer's sole representative must declare the new substance to the Notification Authority before placing it on the market for the first time either alone or as a constituent in a preparation or object from which the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Art. 26 Form and content of the declaration

[1] The declaration must be submitted in quadruplicate. The accompanying letter must be written in an official language and submitted on paper. The information and documents may be written in English instead of in an official language and may be submitted on electronic media instead of on paper.

[2] The declaration must contain the following information and documents:

a. the name and address of the manufacturer;

b. the name and address of the foreign manufacturer if the manufacturer has imported the substance;

81 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

82 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

c. essential data relating to the identity of the substance;

d. the intended uses;

e. the amount of the substance that the manufacturer intends to place on the market each year in Switzerland;

f. proposed classification and labelling;

g. the research programme and a list of the people to whom the substance is to be supplied;

h.[83] a proposed safety data sheet in the case of dangerous substances or PBT or vPvB substances.

3 ...[84]

Section 4: Procedure for Notification and Declaration

Art. 27 Confirmation of receipt and forwarding of the documents

1 The Notification Authority shall confirm to the manufacturer or the sole representative the date on which the notification or declaration was received.

2 If the documents are not obviously incomplete, the Notification Authority shall forward them to the assessment authorities.

Art. 28 Review of the notification or declaration

1 The assessment authorities, within their area of competence, shall assess whether:

a.[85] the submission is complete or if not, whether the reasons given by the notifier are valid;

a. the data is scientifically plausible;

b. the test reports are based on tests meeting the requirements laid down in Article 34.

2 The assessment authorities shall report the results of their review to the Notification Authority.

Art. 29 Additions to the documents

1 If the Notification Authority discovers that the documents are obviously incomplete, it must inform the manufacturer or sole representative accordingly without delay.

83 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
84 Repealed by No I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
85 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[2] If an assessment authority discovers that the documents are incomplete or inaccurate, or that further data or tests are required to assess the dangers associated with the substance in question, it shall inform the Notification Authority accordingly. The Notification Authority shall ask the manufacturer or sole representative to submit additions or corrections.

[2bis] If a robust study summary in accordance with Article 18 paragraph 2 letter b numbers 7–9 does not permit an independent assessment of a specific test, the Notification Authority may request the full study report.[86]

[3] The Notification Authority shall confirm to the manufacturer or the sole representative the date on which the additions and corrections were received.

Art. 30 Acceptance of the notification or declaration

With the agreement of the assessment authorities, the Notification Authority shall order the acceptance of the notification or declaration if the review has shown that the notification or declaration documents are complete and adequate for assessment of the dangers and risks associated with the substance in question.

Section 5: Authorisation to Place Substances on the Market

Art. 31 Placing substances subject to notification requirements on the market

[1] Substances subject to notification requirements may be placed on the market if:

a. the Notification Authority has accepted their notification; or

b. 60 days have elapsed since the confirmed date of receipt of the notification and of any additions or corrections required thereafter, without the Notification Authority having issued any response.

[2] The period referred to in paragraph 1 letter b shall be reduced to 30 days if the notifier has submitted official confirmation that the substance was notified in the EU before 1 June 2008 and that the notification has been accepted.[87]

Art. 32 Placing substances subject to declaration requirements on the market

Substances subject to declaration requirements may be placed on the market if:

a. the Notification Authority has accepted their declaration; or

b. 30 days have elapsed since the confirmed date of receipt of the declaration and of any additions or corrections required thereafter, without the Notification Authority having issued any response.

86 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

87 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

Chapter 3: Requirements for Tests

Art. 33 Principle

[1] Manufacturers must ensure that the conduct of the tests, test methods and assessment of test results are in accordance with the current state of scientific and technical knowledge.

[2] The FDHA, DETEC and the EAER may regulate technical details in their respective areas of competence.

Art. 34[88] Requirements

[1] Tests designed to determine the properties of substances and preparations must be carried out in accordance with:

a.[89] the test methods defined in Regulation (EC) No. 440/2008[90]; or

b. the Guidelines for the Testing of Chemicals drawn up by the Organisation for Economic Cooperation and Development (OECD) of August 2007[91] (OECD Guidelines for the Testing of Chemicals).

[2] Other test methods may be used if:

a. no method is specified in paragraph 1;

b. the manufacturer can show that a specified method for determining a given physicochemical property is not suitable; or

c.[92] the method is recognised in the EU in accordance with Article 13 paragraph 3 of the REACH Regulation[93].

[3] If other test methods are used, the manufacturer must show that these methods:

a. produce valid results; and

b. take due account of animal protection in the case of tests on animals.

[4] Non-clinical tests designed to determine properties that are dangerous to health or the environment must be carried out in accordance with the principles of Good

88 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
89 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
90 Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 142 of 31.5.2008, p. 1; last amended by Regulation (EU) No 640/2012, OJ L 193, 20.7.2012, p. 1.
91 OECD Guidelines for the Testing of Chemicals, August 2007. This text can be accessed on the Internet at www.cheminfo.ch
92 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
93 See footnote to Art. 2 para. 4.

Laboratory Practice (GLP) specified in the Ordinance of 18 May 2005[94] on Good Laboratory Practice.

[5] If certain tests do not comply with GLP principles or do not comply with them fully, the person submitting the test reports must state the reasons. The Notification Authority shall decide whether to accept these test results after consulting the assessment authorities.

Chapter 4: Packaging and Labelling[95]

Section 1:[96] Packaging and Labelling of Dangerous Substances

Art. 34*a* Packaging

Manufacturers making available or supplying dangerous substances to third parties must package them in accordance with Article 35 of the CLP Regulation[97].

Art. 34*b* Labelling

[1] Manufacturers making available or supplying dangerous substances to third parties must label them in accordance with Article 17 paragraph 1, Article 18 with the exception of the last sentence of paragraph 2, Articles 19–23, Article 25 paragraphs 1, 3, 4 and 6, Articles 26–28, Article 29 paragraphs 1–4, Article 31, Article 32 paragraphs 1–5 and Article 33 of the CLP Regulation[98].

[2] In addition to paragraph 1, the labelling must meet the following requirements:

a. The name, address and telephone number of the manufacturer are to be included. In the case of substances imported from an EEA member state and not intended for supply to the general public, the manufacturer's name may be replaced by the name of the person specified in Article 17 paragraph 1 letter a of the CLP Regulation.

b. The labelling must be written in at least two official languages. With the agreement of individual professional final users, a substance for supply to these final users may be labelled in only one official language or in English.

[3] If further labelling elements are required in order to comply with other legislation, these are to be included in the section for supplemental information in accordance with Article 25 of the CLP Regulation.

94 SR **813.112.1**
95 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
96 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
97 See footnote to Art. 2 para. 4.
98 See footnote to Art. 2 para. 4.

4 Where the name in the IUPAC nomenclature[99] exceeds 100 characters, another name may be used, provided that the notification in accordance with Article 64 includes both the name set out in the IUPAC nomenclature and the other name used.

Art. 34*c* Exemptions from labelling requirements

1 The Notification Authority may in consultation with the assessment authorities permit labelling in only one official language for certain substances or groups of substances in cases where labelling in accordance with Article 34*b* is not possible because packages are too small or otherwise unsuitable.

2 It shall issue a ruling or a general ruling in response to a justified request.

3 It shall maintain a list of exemptions granted and make this accessible to the public.

Art. 34*d* Labelling of dangerous substances for export

1 Any person exporting dangerous substances must label them at least with the following information, taking into account the relevant international standards:

a. name of the manufacturer;

b. chemical name or trade name;

c. labels showing the hazards to humans and the environment and the appropriate protective measures.

2 The labelling must be worded in a language accepted by the importing country.

Section 2: Packaging and Labelling of Preparations[100]

Art. 34*e*[101] General provisions

1 Manufacturers making available or supplying preparations to third parties must package and label them in accordance with the following provisions:

a. Articles 35–50, if they are classified exclusively in accordance with Article 10 paragraph 1. Article 34*d* applies mutatis mutandis;

b. Articles 34*a*–34*d*, mutatis mutandis, if they are classified in accordance with Article 10 paragraph 2.

2 Double labelling in accordance with paragraph 1 letters a and b is not permissible.

99 Chemical nomenclature of the International Union of Pure and Applied Chemistry (IUPAC): www.iupac.org

100 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

101 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

Art. 35 Characteristics of packaging

[1] Packaging must be constructed in such a way that the dangerous preparations contained therein do not present any risk to people or the environment during storage or transport.[102]

[2] In particular, packaging must meet the following requirements:

a. it must be so designed and constructed that its contents cannot escape;

b. it must not be damaged by the contents;

c. it must not form harmful or dangerous compounds with the contents;

d. it must safely withstand the normal stresses and strains of handling; in particular, any fastenings must not loosen.

[3] The requirements specified in paragraphs 1 and 2 are deemed to be met if the packaging complies with the regulations concerning transport by post, rail, road, air, water and pipelines.[103]

Art. 36 Design of packaging

Packaging of dangerous preparations sold to the general public must be designed so as not to:[104]

a. attract or arouse the curiosity of children;

b. mislead consumers;

c. lead to confusion with packaging containing foodstuffs, cosmetic products, therapeutic products or animal feedingstuffs.

Art. 37 Special provisions

[1] Containers for preparations sold to the general public must be fitted with child-resistant fastenings if the preparation:

a. is labelled as toxic or corrosive;

b. is labelled as harmful, with the risk phrase R 65; this does not apply to aerosols or containers with a sealed spray attachment;

c. has a methanol (CAS No.[105] 67-56-1) content equal to or greater than 3 per cent or a dichloromethane (CAS No. 75-09-2) content equal to or greater than 1 per cent.[106]

102 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
103 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
104 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
105 Number assigned by the Chemical Abstracts Service (CAS) to facilitate the identification of substances: www.cas.org
106 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

[2] Containers for preparations sold to the general public must carry a tactile warning of danger if the preparation is labelled as toxic, harmful, corrosive, extremely flammable or highly flammable. This does not apply to aerosols labelled only as extremely flammable or highly flammable.[107]

[3] The technical properties of the child-resistant fastenings and tactile warnings of danger must comply with Annex IX to Directive 67/548/EEC.

[4] Aerosol dispensers not covered by the Foodstuffs Act of 9 October 1992[108] are subject both to the packaging provisions of this Ordinance and to Articles 1 and 2 of, and points 2.1, 2.4, 3, 4, 5 and 6 of the Annex to Directive 75/324/EEC[109].[110]

Art. 38 Exemptions

Articles 35 to 37 do not apply to explosives or pyrotechnic devices within the meaning of the Explosives Act of 25 March 1977[111], with the exception of pyrotechnic devices designed to produce toxic gases, smoke or dusts.

Art. 39[112] Labelling of dangerous preparations

[1] The labelling of dangerous preparations must include the following information:

a. the name of the preparation;

b. the manufacturer's name, address and telephone number. In the case of preparations imported from an EEA member state and not intended for supply to the general public, the manufacturer's name may be replaced by the name of the person responsible for placing the preparation on the market in the EEA in accordance with Article 10 point 2.2 of Directive 1999/45/EC[113].

c. the fill quantity, in the case of preparations made available to the general public;

d. the danger symbols and indications of danger in accordance with Annex 1 number 1;

e. the R-phrases in accordance with Annex 1 number 2, indicating special risks;

f. the S-phrases in accordance with Annex 1 number 3, providing safety advice;

107 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
108 SR **817.0**
109 Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, OJ L 147 of 9.6.1975, p. 40; last amended by Directive 2008/47/EC, OJ L 96 of 9.4.2008, p. 15. This text can be accessed on the Internet at www.cheminfo.ch
110 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
111 SR **941.41**
112 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
113 See footnote to Art. 12 para. 1.

g. the chemical name of the dangerous substances in a preparation in accordance with Annex 1 number 4;

Art. 40[114] Labelling of preparations posing particular hazards

[1] In addition to the information required in accordance with Article 39, preparations posing particular hazards are subject to the provisions of Annex 1 number 5.

Art. 41 and **42**[115]

Art. 43[116] Use of an alternative chemical name

[1] Manufacturers of preparations may use an alternative chemical name for a substance:

a. if they demonstrate that disclosing the name of the substance on the label or in the safety data sheet would put the confidential nature of their business, in particular their intellectual property rights, at risk; and

b. if the substance meets the criteria specified in Section 1.4 of Annex I to the CLP Regulation[117].

[2] The alternative chemical name shall be a name that identifies the most important functional groups or serves as an alternative designation.

[3] Manufacturers wishing to use an alternative chemical name must make a request in writing to the Notification Authority.

[4] The use of an alternative chemical name may be requested for a preparation:

a. in a specific composition;

b. with a specific trade name or a specific designation; and

c. reserved for certain uses.

[5] Authorisation to use an alternative chemical name is granted to the manufacturer and is non-transferable.

Art. 44 Requests to use an alternative chemical name[118]

[1] Requests to use an alternative chemical name must contain:[119]

a. the manufacturer's name, address and telephone number;

114 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
115 Repealed by No I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
116 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
117 See footnote to Art. 2 para. 4.
118 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
119 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

b. the following information relating to the substances whose identity is to remain confidential on the label:
   1. the chemical name,
   2. the CAS number,
   3. the EC number;
c. the alternative name of the substance;
d. the reasons for the request;
e. the trade name or designation of the preparation;
f. the information on the constituents in accordance with the provisions relating to the safety data sheet;
g. the classification of the preparation;
h. the labelling of the preparation;
i. the intended uses of the preparation;
j. the physical state;
k. if applicable, the safety data sheet.

[2] The Notification Authority shall decide on the request in agreement with the assessment authorities.

Art. 45[120] Prohibition on misleading labelling

The labelling and presentation of dangerous preparations must not give the impression that they are not dangerous; in particular, they must not be marked with words such as "non-toxic", "not harmful", "environment-friendly", "non-polluting" or "ecological".

Art. 46 Optional labelling

[1] Manufacturers may provide further indications of dangers to the environment and information on protective measures, as shown in Annex 1 number 7, on the packaging of preparations or objects.[121]

[2] If Annex 1 number 7 requires a specific pictogram to be used, manufacturers must not use a different pictogram unless they can demonstrate that it is in common international use.

Art. 47 Implementation of labelling

[1] Labelling information must appear on each package or on a label that is firmly affixed to the packaging. It must be written in at least two official languages and be clearly visible, legible and durable.[122]

120 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
121 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

1bis ...[123]

2 The details of implementation are based on the provisions of Annex 1 number 6.

3 With the agreement of individual professional final users, a preparation for supply to these final users may be labelled in only one official language or in English.[124]

Art. 48[125] Inner and outer packages

1 The provisions of Articles 39 to 47 are deemed to have been met if:

a. the outer package is labelled in accordance with the regulations concerning transport by post, rail, road, air, water and pipelines; and

b. the inner package is labelled in accordance with Articles 39 to 47 before the application of or immediately after the removal of the outer package. Responsibility for packaging and labelling rests with the manufacturer.

2 In the case of a single package, the danger symbols and indications of danger may be omitted provided that the labelling requirements specified in paragraph 1 letter a are met. This does not apply, in the case of preparations, to the danger symbol N and the indication of danger "dangerous for the environment" if they do not appear in this form on the label.

Art. 48*a*[126] Derogations from the labelling requirements[127]

1 The Notification Authority may, after consultation with the assessment authorities, permit derogations from the labelling requirements for certain preparations or groups of preparations and allow these not to be labelled or to be labelled in some other suitable form:

a. if the packages are too small or otherwise unsuitable for labelling in accordance with Articles 39 to 47; or

b. if the preparations are supplied in such small quantities that that they pose no risk to humans or the environment.[128]

2 The Notification Authority shall issue a ruling or a general ruling in response to a justified application.

122 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
123 Inserted by No I of the Ordinance of 28 Feb. 2007 (AS **2007** 821). Repealed by No I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
124 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
125 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
126 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
127 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
128 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

3 The Notification Authority shall maintain a list of the derogations that have been permitted and make it available to the public.

Art. 49[129]

Art. 50[130] Exemptions

1 Articles 39 to 49 do not apply to explosives or pyrotechnic devices (Art. 38), with the exception of pyrotechnic devices designed to produce toxic gases, smoke or dusts.

2 Article 39 does not apply to the following dangerous preparations provided that, in the form in which they are placed on the market, they do not represent a danger either to human health as a result of inhalation, ingestion or skin contact, or to water bodies:[131]

a. metals in massive form,

b. alloys,

c. preparations containing polymers or elastomers.

3 Preparations classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R 65 when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.[132]

Chapter 4*a*: Exposure Scenarios and Safety Data Sheet[133]

Section 1:[134] Exposure Scenarios

Art. 50*a*

1 The manufacturer of an existing substance that fulfils the criteria specified in Article 14 paragraph 4 of the REACH Regulation[135] and is supplied as such to third parties in a total quantity of 10 tonnes per year or more must prepare an exposure scenario for each identified use of the substance.

2 Any person who obtains a substance for which exposure scenarios have been prepared and supplies it to third parties on a commercial basis in quantities of

129 Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).
130 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
131 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
132 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
133 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
134 Inserted by No. I of the Ordinance of 14 Jan. 2009 (AS **2009** 401). Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
135 See footnote to Art. 2 para. 4.

1 tonne per year or more as a substance or in a preparation for a use not described in the safety data sheet must prepare an exposure scenario for this use.

3 Paragraph 2 does not apply in cases where:

a. the exposure scenario for the new use would exclusively cover conditions described in an exposure scenario included in the safety data sheet;

b. the substance is present in the preparation in a concentration below the limits referred to in Article 18 paragraph 3;

c. the substance is used for purposes of product and process-orientated research and development.

4 The exposure scenarios must be prepared in accordance with the provisions of Section 5.1 of Annex I to the REACH Regulation[136].

Section 2: Safety Data Sheet[137]

Art. 51 Purpose

Safety data sheets are designed to enable people handling substances or preparations in a professional or commercial capacity to take the measures required for health protection, occupational safety and environmental protection.

Art. 52[138] Obligation to compile a safety data sheet

Where the provision of a safety data sheet is required under Article 54, the manufacturer must compile a safety data sheet for the following substances and preparations:

a. dangerous substances and preparations;

b. PBT or vPvB substances;

c.[139] substances listed in Annex 7;

d. preparations containing at least one substance that is dangerous to health or to the environment in an individual concentration of ≥ 1.0 per cent by weight (non-gaseous preparations) or ≥ 0.2 per cent by volume (gaseous preparations);

e.[140] preparations containing at least one PBT or vPvB substance in an individual concentration of ≥ 0.1 per cent by weight;

136 See footnote to Art. 2 para. 4.
137 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
138 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
139 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
140 Amended by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).

f.[141] preparations containing at least one substance listed in Annex 7 in an individual concentration of ≥ 0.1 per cent by weight;

g.[142] preparations containing at least one substance for which a workplace exposure limit has been laid down in Directives 2000/39/EC[143], 2006/15/EC[144] or 2009/161/EU[145].

Art. 53[146] Requirements for safety data sheets and their compilation

[1] Safety data sheets must be compiled in accordance with the following requirements:

a. for substances and for preparations classified exclusively in accordance with Article 10 paragraph 1: Annex II to the REACH Regulation, as amended by Article 1 point 1 of Regulation (EU) No 453/2010[147] (corresponding to Annex I to Regulation (EU) No 453/2010);

b. for preparations classified in accordance with Article 10 paragraph 2: Annex II to the REACH Regulation, as amended by Article 1 point 2 of Regulation (EU) No 453/2010 (corresponding to Annex II to Regulation (EU) No 453/2010).

[2] For the information to be provided in accordance with points 1, 7, 8, 13 and 15 of the two versions of Annex II to the REACH Regulation referred to in paragraph 1, the correspondences specified in Annex 5 must be taken into account.

[3] The exposure scenarios included in the chemical safety report (Art. 18*a*) or prepared in accordance with Article 50*a* must be attached to the safety data sheet.

[4] The classification must be indicated in the safety data sheet as follows:

a. in the case of substances: the classification both in accordance with Article 8 paragraph 1 and in accordance with Article 8 paragraph 2;

141 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
142 Inserted by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).
143 Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, OJ L 142 of 16.6.2000, p. 47; last amended by Directive 2009/161/EU, OJ L 338 of 19.12.2009, p. 87. This text can be accessed on the Internet at www.cheminfo.ch
144 Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC; OJ L 38 of 9.2.2006, p. 36. This text can be accessed on the Internet at www.cheminfo.ch
145 Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC, OJ L 338 of 19.12.2009, p. 87. This text can be accessed on the Internet at www.cheminfo.ch
146 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
147 Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 133 of 31.5.2010, p. 1.

b. in the case of preparations labelled according to Article 34*e* paragraph 1 letter b: the classification both in accordance with Article 10 paragraph 1 and in accordance with Article 10 paragraph 2 for the preparation and the constituents to be specified.

[5] The FDHA may, in consultation with DETEC and the EAER, define the technical expertise required for the compilation of safety data sheets.

Art. 54[148] Obligation to provide safety data sheets

[1] Anyone acting in a commercial capacity who supplies substances or preparations referred to in Article 52 to people who handle these in a professional or commercial capacity must provide them with a current safety data sheet.

[2] The safety data sheet must be provided:

a. when supplying a substance or a preparation as defined in Article 52 letters a–c: at the latest at the time it is first supplied, and if requested with other deliveries;

b. when supplying a preparation as defined in Article 52 letters d–g: on request.

[3] In the case of substances and preparations supplied via a retail outlet, the safety data sheet must be provided if this is requested by a professional or commercial customer.

[4] Safety data sheets must be provided as follows:

a. free of charge;

b. in the official languages requested by the customer or, by mutual agreement, in another language; the annex to the safety data sheet may be written in English;

c. on paper or in electronic form; the safety data sheet is to be provided on paper if this is requested by the customer.

Art. 55[149] Updating

[1] If important new information on a substance or preparation becomes available, the manufacturer must update the safety data sheet without delay.

[2] The supplier must make the updated safety data sheet available to all professional or commercial customers supplied with the substance or preparation concerned within the previous twelve months.

[3] Paragraph 2 does not apply to safety data sheets provided through retail outlets.

148 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
149 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

Art. 56 Obligation to retain safety data sheets

Professional or commercial customers are required to retain the safety data sheet for as long as the substance or preparation in question continues to be handled at their workplace.

Art. 56*a*[150]

Art. 56*b*–56*e*[151]

Title 3: Obligations after Placing on the Market

Chapter 1: Taking Account of new Information Relevant to Assessment, Classification and Labelling

Art. 57 Reassessment of substances, preparations and objects

Manufacturers must reassess or further assess substances, preparations and objects containing dangerous constituents and reclassify them where necessary if:

a. they are to be supplied for different purposes;

b. they are to be used in a different way;

c. they are to be used in much larger quantities than before;

d. variations arise in the nature and quantity of impurities, which could have adverse effects on human health or the environment;

e. the evaluation of the risks they pose to human health or the environment needs to be modified in the light of practical experience, new data or new information.

Art. 58 Updating and retention of documents

[1] Manufacturers are required to update documents continuously with new information relevant to health and the environment for as long as they continue to supply the substance, preparation or object containing dangerous constituents.

[2] They must retain or ensure the availability of the main documents used in the assessment and classification, together with the results of the assessment and classification, for at least ten years after the products are last placed on the market. They must retain samples and specimens for as long as their condition allows them to be analysed.

150 Inserted by No I of the Ordinance of 14 Jan. 2009 (AS **2009** 401). Repealed by No I of the Ordinance of 10 Nov. 2010, with effect from 1 Dec. 2010 (AS **2010** 5223).

151 Inserted by No I of the Ordinance of 14 Jan. 2009 (AS **2009** 401). Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).

Chapter 2: Updated Information and Additional Test Reports on new Substances

Art. 59 Updated information

[1] Notifiers must inform the Notification Authority in writing without delay if:

a. the details referred to in Article 18 paragraph 2 letter b numbers 1–6 or Article 26 paragraph 2 change;

b. the relevant substance quantity in accordance with Article 16*a* is likely to have reached one of the thresholds laid down in Article 60 paragraph 1; in this case, the notifier shall specify which tests it intends to conduct in order to produce the additional information specified in Article 60 paragraph 1;

c. the decisive substance quantity in accordance with Article 16*a* has increased or decreased by a factor of more than two compared with the quantity last notified;

d. new information comes to their attention regarding the effects of the substance on human health or the environment;

e. they place the substance on the market for a new use or become aware that this substance is being used for purposes other than those indicated to the Notification Authority;

f. they compile, or have compiled for them, test reports going beyond the technical dossier referred to in Article 18 paragraph 2 letter b for the substance in question;

g. they are able to obtain other test reports going beyond the technical dossier referred to in Article 18 paragraph 2 letter b.[152]

[2] Sole representatives must ensure that they have access to updated data, particularly as regards the quantities of substances imported annually by the importers they represent.

[3] Importers represented by a sole representative for notification of a new substance must inform that representative annually of the imported quantities of the substance concerned.

Art. 60[153] Information to be submitted based on quantities

[1] Notifiers of a substance must provide the Notification Authority with the following additional information based on the decisive substance quantity in accordance with Article 16*a*:

152 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
153 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

a. for quantities of 10 tonnes per year or more: the information mentioned in Annex 3 number 8 letter b and number 9 letter b and a chemical safety report in accordance with Article 18*a*;

b. for quantities of 100 tonnes per year or more: the information mentioned in Annex 3 number 7 letter b, number 8 letter c and number 9 letter c and a chemical safety report in accordance with Article 18*a*;

c. for quantities of 1,000 tonnes per year or more: the information mentioned in Annex 3 number 8 letter d and number 9 letter d and a chemical safety report in accordance with Article 18*a*.

[2] After receiving the information specified in Article 59 paragraph 1 letter b, the Notification Authority shall in accordance with Article 23 inform the notifier of the data that it already holds.

[3] If the risks associated with a given substance cannot be adequately evaluated, the Notification Authority shall, if so requested by an assessment authority, require the notifier to submit additional information or carry out additional tests relating to the substance or its transformation products.

[4] The Notification Authority, after consulting the notifier and with the agreement of the assessment authorities, shall draw up a timetable for carrying out the additional tests.

[5] If the notifier fails to submit the additional test reports by the specified deadline, the Notification Authority may arrange for the required tests to be carried out at the notifier's expense and, if necessary, prohibit the notifier from continuing to place the relevant substance on the market.

Chapter 3: Obligation to Register

Art. 61[154] Substances and preparations subject to registration requirements

Manufacturers of the substances and preparations specified in Article 52 must register them with the Notification Authority within 3 months after first placing them on the market, irrespective of whether a safety data sheet has to be compiled for them.

Art. 62 and **63**[155]

Art. 64[156] Content of the registration application

The registration application must contain the following data:

154 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
155 Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).
156 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

a. the manufacturer's name and address;

b. the name of the person responsible for placing the substance or preparation on the market in the EEA in accordance with Article 10 point 2.2 of Directive 1999/45/EC[157] or Article 17 paragraph 1 letter a of the CLP Regulation[158], if the manufacturer's identity is not mentioned on the label;

c. in the case of substances:
   1. the chemical name according to Article 18 paragraph 2 letters a–d of the CLP Regulation,
   2. the CAS number,
   3. the EC number,
   4. the classification and labelling;
   5. the intended uses,
   6. in the case of substances dangerous to the environment: the quantity likely to be placed on the market annually according to one of the following categories: less than 1 tonne, 1–10 tonnes, 10–100 tonnes, more than 100 tonnes,
   7. in the case of nanomaterials: the composition, particle form and mean particle size and, where available, the number size distribution, specific surface area by volume, crystal structure, aggregation status, surface coating and surface functionalisation,
   8. an indication of whether the substance is considered to be PBT or vPvB,
   9. the chemical safety report available in the EEA, provided the manufacturer can reasonably be expected to obtain it;

d. in the case of preparations:
   1. the trade name,
   2. data relating to the constituents in accordance with the provisions concerning the safety data sheet,
   3. the classification and labelling,
   4. the intended uses,
   5. the physical state.
   6. in the case of preparations dangerous to the environment: the quantity likely to be placed on the market annually according to one of the following categories: less than 1 tonne, 1–10 tonnes, 10–100 tonnes, more than 100 tonnes,
   7. in the case of preparations containing nanomaterials: the composition of the nanomaterials, the particle form and mean particle size and, where available, the number size distribution, specific surface area by volume, crystal structure, aggregation status, surface coating and surface functionalisation.

157 See footnote to Art. 12 para. 1.
158 See footnote to Art. 2 para. 4.

Art. 65[159] Extended registration application

[1] In the case of dangerous preparations sold to the general public, the Notification Authority must be informed of the full composition. Non-dangerous constituents may be designated in accordance with Part B of Annex VI to Directive 1999/45/EC[160] either by a name that identifies the most important functional groups or by an alternative name.

Art. 66[161] Form of the registration application and the extended registration application

The registration application and extended registration application are to be submitted as follows:

a. using an electronic form or, where this is justified, on a paper form which can be processed electronically;

b. in an official language or in English.

Art. 67[162] Modifications

[1] Any modifications to the data referred to in Articles 64 and 65 must be reported within 3 months.

[2] If the quantity of substances and preparations dangerous to the environment actually supplied in a year is outside the registered category of quantities placed on the market, the quantity placed on the market in the previous year must be reported by 31 March of the following year in accordance with the categories specified in Article 64 letter c number 6 and letter d number 6.

Art. 68[163] Special form of compliance with the obligation to register

The requirements to register preparations in accordance with Article 61 are deemed to have been met if a request to use an alternative chemical name (Art. 44) has been submitted and the Notification Authority possesses the information required by Article 64 letters a, b and d and, if applicable, Article 65.

Art. 69 Exemptions from the obligation to register

The registration requirements specified in this Chapter do not apply to:

a.[164] …

159 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
160 See footnote to Art. 12 para. 1.
161 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
162 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
163 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

b. intermediates;

c.[165] substances and preparations which are placed on the market solely for purposes of analysis, research or education, or which are subject to research and development;

d.[166] substances and preparations used exclusively for foodstuffs, therapeutic products or animal feedingstuffs;

e. fertilisers which require authorisation from the Federal Office for Agriculture (FOAG) or have to be notified to the FOAG under the Fertiliser Ordinance of 10 January 2001[167];

f.[168] explosives and pyrotechnic devices which require authorisation under the Explosives Ordinance of 27 November 2000[169];

g.[170] substances obtained in Switzerland;

h.[171] preparations obtained in Switzerland and supplied in packaging other than that intended by the original manufacturer, provided that:

1. the trade name, composition and intended use are unchanged, and
2. the name of the original manufacturer is also indicated;

i.[172] gas mixtures consisting exclusively of registered gases;

j.[173] non-dangerous preparations in packages containing no more than 200 ml, if they are manufactured in Switzerland and supplied directly to final users by the manufacturer;

k.[174] preparations placed on the market in quantities of less than 100 kg per year and intended exclusively for professional users.

164 Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).
165 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
166 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
167 SR **916.171**
168 Inserted by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
169 SR **941.411**
170 Inserted by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
171 Inserted by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
172 Inserted by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
173 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
174 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

Title 4: Handling of Substances, Preparations and Objects
Chapter 1: General Provisions

Art. 70 Taking account of the information provided by the manufacturer

[1] Substances, preparations and objects may be promoted, offered or supplied professionally or commercially only for the uses and methods of disposal stated by the manufacturer.

[2] The advice and instructions given on the package and in the safety data sheet must be taken into account.

Art. 71 Environmental release

[1] Substances and preparations may be released directly into the environment only to the extent that is necessary for the intended use.

[2] To this end, users must:

a. use equipment allowing correct and accurate application;

b. take steps to prevent substances and preparations, as far as possible, from entering surrounding areas or water bodies;

c. take steps to ensure that, as far as possible, animals, plants, their biocoenoses and habitats are not threatened.

[3] Preparations may be released directly into the environment only for the uses specified by the manufacturer.

Art. 72 Storage

[1] When substances and preparations are stored, the advice and instructions given on the package and, if applicable, in the safety data sheet must be taken into account.

[2] Dangerous substances and preparations and their containers must be protected against hazardous impacts, especially those of a mechanical nature.

[3] Dangerous substances and preparations must be clearly identifiable and kept separate from other goods. No foodstuffs, animal feedstuffs or therapeutic products may be kept in the immediate vicinity.

[4] Paragraphs 1 to 3 also apply to objects from which substances or preparations are released in quantities that may endanger human health or the environment.

[5] Substances and preparations that may react dangerously with each other must be stored separately.

[6] Dangerous substances and preparations that are not commercially supplied may only be filled and stored in containers meeting the following requirements:

a. the packaging must not be capable of being confused with packaging containing foodstuffs, cosmetics, therapeutic products or feedstuffs;

b. the name of the substance or preparation must be given in the labelling; and

c. the construction of the packaging must comply with the requirements of Article 35.[175]

Art. 73[176] Specific obligations when supplying substances and preparations

Anyone who supplies a substance or preparation in a commercial capacity and is required to provide a safety data sheet to the customer must be familiar with and capable of interpreting the content of the safety data sheet.

Art. 74 Chemicals contact person

[1] Companies and educational establishments must notify the cantonal enforcement authorities of their chemicals contact person, to be appointed under Article 25 paragraph 2 of the Chemicals Act.

[2] The FDHA sets down the rules for mandatory notification in accordance with paragraph 1; it defines the form and content of the notification.

[3] It defines the requirements that the chemicals contact person must meet, particularly with regard to technical qualifications and operational responsibilities.

Art. 75[177] Advertising

[1] Advertising for substances, preparations and objects must not give a misleading impression as to the risks posed to human health and the environment or as to their environmental acceptability, and must not encourage inappropriate or illegitimate use or disposal.

[2] Terms such as “degradable”, “environmentally harmless”, “environment-friendly” and “water-friendly” may be used in advertising only if the properties thus described are at the same time explained in more detail.

[3] Anyone who advertises dangerous substances or preparations that the general public can purchase without seeing the labelling beforehand must indicate their hazardous properties in a comprehensible and clearly legible or audible manner.

[4] Paragraph 3 also applies to preparations labelled in accordance with number 5 of Annex 1 to this Ordinance or Article 25 paragraph 6 of the CLP Regulation[178].

[5] Substances and preparations are not to be promoted for uses for which they must not be placed on the market.

175 Inserted by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).
176 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
177 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
178 See footnote to Art. 2 para. 4.

Chapter 2: Handling of Dangerous Substances and Preparations in Groups 1 and 2[179]

Art. 76[180] Dangerous substances and preparations in Groups 1 and 2

Dangerous substances and preparations are deemed to belong to Group 1:

a. if their labelling in accordance with the CLP Regulation[181] contains at least one element specified in number 1.1 of Annex 6 to this Ordinance; or

b. if they are not yet labelled in accordance with the CLP Regulation and their labelling contains at least one element specified in number 2.1 of Annex 6 to this Ordinance.

2 Dangerous substances and preparations are deemed to belong to Group 2:

a. if their labelling in accordance with the CLP Regulation contains at least one element specified in number 1.2 of Annex 6 to this Ordinance; or

b. if they are not yet labelled in accordance with the CLP Regulation and their labelling contains at least one element specified in number 2.2 of Annex 6 to this Ordinance.

Art. 77[182] Storage

1 For the storage of substances or preparations in Groups 1 and 2, Article 72 applies.

2 Anyone storing substances or preparations in Groups 1 and 2 must ensure that they are not accessible to unauthorised persons.

3 Substances and preparations in Groups 1 and 2 which are not commercially supplied may only be filled and stored in containers if these are labelled with the appropriate danger symbols or hazard pictograms.

Art. 78[183] Exclusion of self-service

1 Substances and preparations in Group 2 which are intended for the general public must not be offered on a self-service basis.

2 Paragraph 1 does not apply to motor fuels.

179 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
180 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
181 See footnote to Art. 2 para. 4.
182 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
183 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

Art. 79[184] Supply restrictions

[1] Substances and preparations in Group 1 must not be supplied to the general public.

[2] Substances and preparations in Groups 1 and 2 may be commercially supplied only to adults.

[3] Paragraph 2 does not apply to legal minors who have to handle these substances or preparations in a professional or commercial capacity.

[4] Paragraphs 1 and 2 do not apply to motor fuels.

Art. 80[185] Special obligations with regard to supply

[1] Anyone who commercially supplies a substance or preparation in Group 1 must inform the purchaser expressly of the precautions required and the correct method of disposal.

[2] Anyone who commercially supplies a substance or preparation in Group 2 to the general public must inform the purchaser in an appropriate manner, at the time of supply, of the precautions required and the correct method of disposal.

[3] Substances and preparations may be supplied in accordance with paragraph 2 only to persons who can be assumed by the supplier to be capable of sound judgement and able to comply with the duty of care under Article 8 of the Chemicals Act and the requirements set out in Article 28 of the EPA.

[4] The obligations specified in paragraphs 1 and 2 do not apply to the supply of motor fuels.

Art. 81 Knowledge required to supply

[1] Special knowledge is required by anyone who, in a commercial capacity:

a. supplies substances and preparations in Group 1 to professional final users;

b. supplies substances and preparations in Group 2 to the general public.[186]

[2] The FDHA may regulate:

a. how the knowledge requirements are to be met; in this connection, it takes into account professional training and experience;

b. the content, duration and organisation of courses for people seeking to acquire such knowledge.

[3] Article 11 of the Chemical Risk Reduction Ordinance of 18 May 2005[187] (ORRChem) applies mutatis mutandis[188].

184 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
185 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
186 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
187 SR **814.81**

4 Paragraph 1 does not apply to motor fuels.[189]

Art. 82[190] Theft, loss, erroneous placing on the market

1 In the event of theft or loss of substances or preparations in Group 1, the person suffering the theft or loss must notify the police without delay.

2 The police must inform the cantonal authority responsible for enforcing this Ordinance as well as the Federal Office of Police.

3 Anyone who erroneously places on the market a substance or a preparation in Group 1 or 2 must immediately inform the cantonal authority responsible for enforcing this Ordinance and provide the following information:

a. all the data required for precise identification of the substance or preparation;

b. a comprehensive description of the danger which the substance or preparation may pose;

c. all the available information as to the source from which the substance or preparation was obtained and, if the substance or preparation has not been supplied directly to users, to whom the substance or preparation has been supplied;

d. the measures taken to avert any danger, such as warnings, suspension of sales, withdrawal from the market or recall.

4 The cantonal authority must decide whether the public needs to be warned of any danger.

Art. 83[191] Samples

Substances and preparations in Groups 1 and 2 may be provided for promotional purposes only to professional or commercial users.

Art. 83*a*[192] Substances and preparations intended for self-defence

1 For the handling of substances and preparations intended for self-defence, Article 77, Article 79 paragraphs 2 and 3, Article 80 paragraphs 2 and 3, Article 81 paragraph 1 letter b, Article 82 paragraphs 3 and 4 and Article 83 apply mutatis mutandis.[193]

188 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
189 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
190 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
191 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
192 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
193 Revised with effect from 15 Jan. 2013 (AS **2013** 201).

2 Substances and preparations intended for self-defence must not be offered on a self-service basis.

Chapter 3:[194] Handling of Substances of Very High Concern

Art. 83*b* List of substances of very high concern

1 Substances referred to in Article 57 of the REACH Regulation[195] are deemed to be of very high concern if they are included in Annex 7 (candidate list).

2 The FOEN shall decide, in consultation with the FOPH and SECO, whether a candidate list substance listed in Annex XIV to the REACH Regulation is to be included in Annex 1.17 to the ORRChem[196].

Art. 83*c* Objects containing substances of very high concern

1 Anyone who commercially supplies an object containing a substance of very high concern in a concentration greater than 0.1 % by weight must provide the customer with the following information:

a. the name of the substance concerned;

b. all the information required to allow safe use of the object, insofar as this is available to the supplier.

2 This information must be provided free of charge:

a. to professional or commercial customers: without being so requested;

b. to private customers: on request within 45 days.

Title 5: Data Processing

Art. 84 Register of products

1 The Notification Authority shall maintain a register of substances and preparations that fall within the scope of the following Ordinances:

a. this Ordinance;

b. the ORRChem[197];

c. the Biocidal Products Ordinance of 18 May 2005[198];

d. the Plant Protection Products Ordinance of 18 May 2005[199].

194 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
195 See footnote to Art. 2 para. 4.
196 SR **814.81**
197 SR **814.81**
198 SR **813.12**

[2] The register is compiled on the basis of data:

a. that has been collected or produced by a Swiss authority under one of the ordinances cited in paragraph 1;

b. that is made available by foreign authorities or by international organisations.

Art. 85 Confidential data

[1] The enforcement authorities shall treat data as confidential when an interest in its confidentiality is worthy of protection, unless there is an overriding public interest in its disclosure.

[2] The Notification Authority shall designate the confidential data in consultation with the assessment authorities. It shall designate it before sending it on to the competent cantonal or federal authorities cited in Article 87 paragraph 2.

[3] In particular, the interest in maintaining commercial/manufacturing secrecy, including information on the full composition of a substance or preparation and the quantities placed on the market, shall be deemed worthy of protection.

[4] If the Notification Authority discovers that data deemed to be confidential has subsequently been disclosed by lawful means, this data shall no longer be treated as confidential.

[5] The following are not deemed confidential under any circumstances:

a. the trade name;

b. the name and address of the person subject to notification, declaration or registration requirements;

c. the physicochemical properties defined in Annexes VII A, VII B, VII C and VII D to Directive 67/548/EEC;

d. procedures for proper disposal, for possible recycling or reuse, and for other ways of rendering materials harmless;

e. the summary of results of toxicological and ecotoxicological tests;

f. the degree of purity of a substance and the identity of the impurities and additives that are relevant for classification;

g. recommendations regarding precautions during use and emergency measures in the event of an accident;

h. information that appears in the safety data sheet;

i. suitable analytical methods for determining the exposure of human beings and presence in the environment.

199 [AS **2005** 3035 4097 5211, **2006** 4851, **2007** 821 No. III 1469 Annex 4 No. 54 1843 4541 6291, **2008** 2155 4377 Annex 5 No. 11 5271, **2009** 401 Annex No. 3 2845, **2010** 2101. AS **2010** 2331 Art. 84]. See now the Ordinance of 12 May 2010 (SR **916.161**).

[6] The Notification Authority and assessment authorities may allow public access to data in the register of products which is not deemed confidential under any circumstances.

Art. 86 Data to be passed on to the Notification Authority and the assessment authorities

The following data concerning substances, preparations and objects must be passed on to the Notification Authority and the assessment authorities if requested and if necessary for enforcement of this Ordinance:

a. data collected by the FOAG under:
   1. the Fertilisers Ordinance of 10 January 2001[200],
   2. the Animal Feedstuffs Ordinance of 26 May 1999[201],
   3. the Plant Protection Products Ordinance of 18 May 2005[202];

b.[203] data on contaminants and constituents in foodstuffs and on substances in articles of daily use collected by the FOPH and by the Federal Food Safety and Veterinary Office under the Foodstuffs Ordinance of 1 March 1995[204];

c.[205] data collected by the Federal Customs Administration from customs declarations;

d. data collected by SECO, by the Swiss National Accident Insurance Fund (SUVA) or by cantonal employment inspectorates under legislation on the protection of workers;

e. data collected by the poisons information centre (Art. 91);

f. data collected by examining bodies under Article 12 paragraph 3 of the ORRChem[206];

g. data collected by cantons in connection with the enforcement of this Ordinance or of other legislation governing the protection of human health or the environment against substances, preparations or objects.

200 SR **916.171**
201 [AS **1999** 1780 2748 Annex 5 No. 6, **2001** 3294 No. II 14, **2002** 4065, **2003** 4927, **2005** 973 2695 No. II 19 5555, **2007** 4477 No. IV 70, **2008** 3655 4377 Annex 5 No. 14, **2009** 2599, **2011** 2405]. See now the Ordinance of 26 Oct. 2011 (SR **916.307**).
202 [AS **2005** 3035 4097 5211, **2006** 4851, **2007** 821 No. III 1469 Annex 4 No. 54 1843 4541 6291, **2008** 2155 4377 Annex 5 No. 11 5271, **2009** 401 Annex No. 3 2845, **2010** 2101. AS **2010** 2331 Art. 84]. See now the Ordinance of 12 May 2010 (SR **916.161**).
203 Amended by No I 3 of the Ordinance of 4 Sept. 2013 (Reorganisation in the field of Food Safety and Veterinary Medicine), in force since 1 Jan. 2014 (AS **2013** 3041).
204 [AS **1995** 1491, **1996** 1211, **1997** 292 1145 1198 Art. 24, **1998** 108, **1999** 303 No I 8 1848, **2002** 573, **2003** 4915 No II, **2004** 457 3035 3065 No II 1, **2005** 1057 1063 2695 No II 15. AS **2005** 5451 Annex 2 No I 1]. See the Foodstuffs and Utility Articles Ordinance of 23 Nov. 2005 (SR **817.02**).
205 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
206 SR **814.81**

Art. 87 Exchange of information and data

[1] The Notification Authority and assessment authorities must, insofar as is required for the performance of their duties, make available to each other the data that they have collected or have had collected on their behalf under this Ordinance or any other legislation governing the protection of human health or the environment against substances, preparations or objects. To this end, they may establish automated retrieval procedures.

[2] The Notification Authority and assessment authorities must make available to the cantonal and federal authorities responsible for enforcing legislation governing the protection of human health or the environment against substances, preparations or objects the data necessary for the performance of their duties. To this end, they may establish automated retrieval procedures.

[2bis] The Notification Authority may make data concerning manufacturers and the substances or preparations that they have placed on the market accessible to the authorities listed below, if these authorities require the data in order to perform their duties:

a. the assessment authorities;

b. the customs authorities;

c. the cantonal authorities specified in paragraph 2;

d. the poisons information centre (Art. 91).[207]

[3] The Notification Authority and assessment authorities may, in special cases, pass on data relating to substances, preparations and objects to bodies other than those cited in paragraph 2, if these bodies require the data in order to perform their duties.

[4] Confidential data relating to the composition of preparations may only be passed on under paragraphs 2, 2[bis] and 3 if this is required by a criminal prosecution authority or if the data serves to answer medical queries, particularly in cases of emergency or to prevent an imminent danger to human life or health or to the environment.[208]

[5] The cantons must inform the Notification Authority of the results of surveys and analyses regarding the quality of indoor air and pass on available data on indoor air to the Notification Authority.

Art. 88 Passing-on of data to other countries and to international organisations

[1] The Notification Authority and assessment authorities may pass on data that is not confidential to foreign authorities and institutions, and to international organisations.

[2] They may pass on confidential data if:

207 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
208 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

a. this is required by international agreements or decisions of international organisations; or

b. it is necessary to prevent an imminent danger to human life or health or to the environment.

Title 6: Enforcement

Chapter 1: Confederation

Section 1: Organisation

Art. 89 Notification Authority and steering committee

[1] The Notification Authority is administratively attached to the FOPH.

[2] A steering committee is appointed for the Notification Authority. It is composed of the directors of the following federal offices:

a. FOPH;

b. FOAG;

c. FOEN;

d. SECO.

[3] The steering committee has the following duties and powers:

a. appointing the management of the Notification Authority;

b. defining the strategy of the Notification Authority;

c. inspection and application rights concerning the budget of the Notification Authority.

[4] The steering committee makes decisions by consensus.

Art. 90 Assessment authorities

The assessment authorities are:

a. the FOPH, for matters concerning the protection of human life and health;

b. the FOEN, for matters concerning the protection of the environment and indirect protection of human beings;

c. SECO, for matters concerning the protection of workers.

Art. 91 Poisons information centre

[1] The poisons information centre established by Article 30 of ChemA is the Swiss Toxicological Information Centre in Zurich (STIZ).

[2] The FOPH shall enter into an agreement with the STIZ setting the amount of remuneration that it receives for the services it provides under Article 30 paragraph 2 of ChemA.[209]

Art. 92 Expert Committee for Chemicals

[1] The FDHA may, in consultation with DETEC and the EAER, appoint an Expert Committee for Chemicals.

[2] The Expert Committee for Chemicals shall be composed of specialists from federal and cantonal bodies, from the fields of science, business and consumer protection and from interested groups.

[3] It shall advise the federal departments on fundamental questions of legislation and enforcement concerning substances and preparations and is authorised to put forward proposals. It may call in external experts for consultation.

Art. 93[210]

Section 2: Review of Existing Substances

Art. 94

[1] The assessment authorities may review any existing substances which:

a. represent a particular risk to human life or health or to the environment, owing to the quantities manufactured or placed on the market or owing to their dangerous nature or the dangerous nature of their secondary products or wastes; or

b. are included in an international existing substances programme.

[2] If an existing substance is to be reviewed, the Notification Authority, at the request of an assessment authority, shall require all the manufacturers concerned to provide the following information:

a. the name and address of the manufacturer, and the name and address of the foreign manufacturer if the manufacturer imports the substance;

b. all documents used in assessing and establishing the hazardous properties of the substance;

c. the known uses;

d. information on the quantities placed on the market by the manufacturers.

209 Amended by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

210 Repealed by No I 7.2 of the Ordinance of 9 Nov. 2011 (Review of Extra-Parliamentary Commissions), with effect from 1 Jan. 2012 (AS **2011** 5227).

e.[211] the registration dossier that was submitted to the European Chemicals Agency, provided it is available and the notifier can reasonably be expected to obtain it.

[3] If requested by an assessment authority, the Notification Authority shall request one of the manufacturers to carry out investigations or studies. The costs incurred by the manufacturer shall be borne jointly by all the manufacturers concerned.

Section 3: Review of Self-Regulation and Monitoring

Art. 95 Review of self-regulation

[1] The assessment authorities must review, in their area of competence, for substances, preparations and objects:

a. the assessment and classification;

b. the information that appears in the safety data sheet.

[2] They may instruct the Notification Authority:

a. to verify the composition and the physicochemical properties of substances, preparations and objects;

b. to ask cantonal enforcement authorities to take samples.

[3] If there is reason to suppose that the assessment or classification has not been carried out or has not been carried out correctly, the Notification Authority, at the request of an assessment authority, must require the manufacturer concerned to provide:

a. all the documents used in establishing the hazardous properties or in the assessment;

b. the safety data sheet, if appropriate.

[4] At the request of an assessment authority, the Notification Authority must require the manufacturer to perform tests or additional assessments if there are indications that:

a. substances or preparations and their secondary products or wastes may endanger human health or the environment;

b. objects, their secondary products or their wastes may endanger the environment.

[5] Moreover, the enforcement authorities have the powers assigned to them by Article 42 of the Chemicals Act and, in the case of a danger to the environment, also Article 41 of the Chemicals Act.

[211] Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).

[6] If a manufacturer does not comply with an official order, the Notification Authority must, if so requested by an assessment authority, prohibit it from continuing to supply the substances, preparations or objects concerned.

[7] As regards cosmetic products, and raw materials and additives intended exclusively for these products, the body responsible for these products must order the necessary measures. The participation of the FOEN is governed by Articles 62*a* and 62*b* of the Federal Act of 21 March 1997[212] on the Organisation of the Government and the Administration.

Art. 96 Monitoring with regard to national defence

In matters concerning national defence, the Notification Authority must examine, in consultation with the assessment authorities, whether the provisions of this Ordinance are being respected.

Art. 97 Monitoring of imports and exports

[1] Customs offices must check, at the request of the Notification Authority, whether substances, preparations or objects comply with the provisions of this Ordinance.[213]

[2] The assessment authorities may call upon the Notification Authority to submit a request as defined in paragraph 1.

[3] In cases of suspected infringement, the customs offices are authorised to detain goods at the border and call in the other enforcement authorities in accordance with this Ordinance. These authorities must carry out further investigations and take the necessary measures.[214]

Section 3*a*:[215] Adaptations to EU legislation

Art. 97*a*

In consultation with the FOEN and SECO, the FOPH shall adapt Annex 7, taking account of any amendments to the candidate list for eventual inclusion in Annex XIV to Regulation (EC) No 1907/2006 referred to in Article 59 paragraph 1 of the REACH Regulation[216].

212 SR **172.010**
213 Amended by Annex 4 No 41 of the Customs Ordinance of 1 Nov. 2006, in force since 1 May 2007 (AS **2007** 1469).
214 Amended by Annex 4 No 41 of the Customs Ordinance of 1 Nov. 2006, in force since 1 May 2007 (AS **2007** 1469).
215 Inserted by No. I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401). Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
216 See footnote to Art. 2 para. 4.

Section 4: Delegation of Duties and Powers to Third Parties

Art. 98

[1] The competent federal bodies may delegate to appropriate public corporations or private persons all or some of the duties and powers assigned to them by this Ordinance.

[2] To the extent that enforcement of health protection is concerned, delegation is limited to the following:

a. review of self-regulation;

b. assessment as part of a review of notification and updated information;

c. provision of information under Article 28 of the Chemicals Act;

d. risk assessment under Article 16 of the Chemicals Act.

Section 5: Charges

Art. 99

The obligation to pay charges and the calculation of charges for administrative actions by the federal enforcement authorities in accordance with this Ordinance is based on the Chemical Charges Ordinance of 18 May 2005[217].

Chapter 2: Cantons

Section 1: Further Inspection

Art. 100 Duties of the cantonal enforcement authorities

[1] By means of random sampling, the cantonal enforcement authorities must inspect substances, preparations and objects placed on the market.

[2] Within the framework of these inspections, the cantonal enforcement authorities must verify:

a. that the notification, declaration and registration requirements (Articles 16, 25, 61, 67 and 68) and the provisions governing updated information (Art. 59) have been respected;

b. that packaging conforms to the provisions on packaging (Articles 34*a* and 34*e*–37);

c. that labelling conforms to the provisions on labelling (Articles 34*b*, 39–50 and Annex 1);

217 SR **813.153.1**

d. that the requirements concerning the provision, updating and retention of the safety data sheet (Articles 54–56) are being complied with and that the information in the safety data sheet is not obviously incorrect;

e. that the provisions on advertising (Art. 75) and samples (Art. 83) are being respected.

f. that the requirement to provide information when supplying objects containing substances of very high concern (Art. 83*c*) has been complied with.[218]

Art. 101 Cooperation between the cantonal and federal enforcement authorities

[1] The Notification Authority must, on its own initiative or at the request of an assessment authority, instruct the cantonal enforcement authorities to inspect certain substances, preparations or objects, especially in accordance with Article 95 paragraph 1.

[2] The cantonal enforcement authorities must collect samples at the request of the Notification Authority.

[3] If the inspections identify serious concerns, the authority that performed the inspections must inform the Notification Authority and the authorities responsible for orders under Article 102.

[4] If there are grounds for suspecting incorrect classification, the authority that performed the inspections must inform the Notification Authority.

Art. 102[219] Orders of cantonal enforcement authorities

If the inspection reveals infringements of the provisions referred to in Article 100 paragraph 2 and Article 101 paragraph 1, the competent authority of the canton in which the infringing party is domiciled or has its registered office must order the measures which need to be taken.

Section 2: Monitoring of Handling and Promotion of Environmentally Sound Practices

Art. 103

[1] The cantonal enforcement authorities must monitor compliance with the specific provisions relating to handling (Articles 70–74 and 76–82). Article 25 paragraph 1 second sentence of the Chemicals Act applies accordingly.

[2] The cantons must promote environmentally sound practices.

218 Amended by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
219 Amended by No I of the Ordinance of 28 Feb. 2007, in force since 1 April 2007 (AS **2007** 821).

Title 7: Final Provisions
Chapter 1: Transitional Provisions

Art. 104-109[220]

Art. 110 Knowledge required to supply and chemicals contact person

The FDHA, in consultation with DETEC and the EAER, shall issue the transitional provisions on:

a. the requirements concerning knowledge required for the supply of particularly dangerous substances and preparations;

b. the requirements concerning the chemicals contact person.

Art. 110*a*[221]

Art. 110*b*[222] Transitional provisions concerning the Amendment of 14 January 2009

[1] and [2]…[223]

[3] The manufacturer must comply with the requirements of Article 50*a* relating to the preparation of exposure scenarios by:

a.[224] …

b. 1 June 2013 for substances that are placed on the market in quantities of 100 tonnes per year or more;

c. 1 June 2018 for substances that are placed on the market in quantities of 10 tonnes per year or more.

Art. 110*c*[225] Transitional provisions concerning the Amendment of 10 November 2010

[1] Substances that have been packaged and labelled in accordance with Articles 35–50 before 1 December 2012 may:

a. be placed on the market by the manufacturer until 30 November 2013;

220 Repealed by No I of the Ordinance of 14 Jan. 2009, with effect from 1 Feb. 2009 (AS **2009** 401).
221 Inserted by No I of the Ordinance of 28 Feb. 2007 (AS **2007** 821). Repealed by No I of the Ordinance of 10 Nov. 2010, with effect from 1 Dec. 2010 (AS **2010** 5223).
222 Inserted by No I of the Ordinance of 14 Jan. 2009, in force since 1 Feb. 2009 (AS **2009** 401).
223 Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).
224 Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).
225 Inserted by No I of the Ordinance of 10 Nov. 2010, in force since 1 Dec. 2010 (AS **2010** 5223).

b. be supplied to final users until 30 November 2014.

2 Preparations that have been packaged and labelled in accordance with Articles 35–50 before 1 June 2015 may:

a.[226] …

b. be supplied to final users until 31 May 2017.

3 …[227]

Art. 110*d*[228] Transitional provisions concerning the Amendment of 7 November 2012

1 Where changes to packaging or labelling are required by the Amendment of 7 November 2012, substances that have been packaged and labelled according to the provisions of the CLP Regulation as last amended by Regulation (EC) No 790/2009[229] may:

a. be placed on the market by the manufacturer until 30 November 2013;

b. be supplied to final users until 30 November 2014.

2 Preparations referred to in Article 10 paragraph 2 may be classified according to the provisions of the CLP Regulation as specified in paragraph 1 until 31 May 2015.

3 Preparations that have been packaged and labelled according to the provisions of the CLP Regulation as specified in paragraph 1 may:

a.[230] …

b. be supplied to final users until 31 May 2017.

4 Requests to use an alternative chemical name in accordance with Article 44 may be submitted in accordance with Article 15 of Directive 1999/45/EC[231] until 31 May 2015.

5 In the case of substances and preparations for which a safety data sheet has been compiled under existing law, the manufacturer must comply with the obligations specified in Article 53 paragraph 1 by 30 November 2014.

226 Repealed by Annex 11 No 1 of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).
227 Repealed by No I of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).
228 Inserted by No I of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
229 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1; last amended by Regulation (EC) No 790/2009, OJ L 235, 5.9.2009, p. 1.
230 Repealed by Annex 11 No 1 of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).
231 See footnote to Art. 12 para. 1.

6 In the case of preparations that were placed on the market before 1 December 2012 and were not subject to registration requirements, the manufacturer must comply with the obligations specified in Article 61 by 30 November 2013.

7 Substances and preparations as specified in Article 78 paragraph 1 which were placed on the market before 1 December 2012 and for which self-service is now prohibited on account of one of the following labelling elements may continue to be offered on a self-service basis until 30 November 2013:

a. EUH029, EUH031 or EUH032 in accordance with Annex 6 number 1.2 letter f; or

b. R29, R31 or R32 in accordance with Annex 6 number 2.2 letter f.

Chapter 2: Commencement

Art. 111

This Ordinance comes into force on 1 August 2005.

Annex 1[232]
(Art. 39, Art. 40, Art. 46, Art. 47 para. 2, Art. 100 para. 2 let. c)

Labelling of preparations

1 Dangers

1.1 Danger symbols and indications of danger

[1] The following danger symbols and indications of danger must be used for labelling of dangerous preparations:

E

Explosive

O

Oxidising

F+

Extremely flammable

F

Highly flammable

N

Dangerous for the environment

T+

Very toxic

T

Toxic

Xn

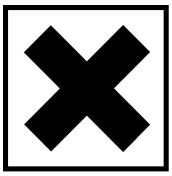
Harmful

C

Corrosive

232 Amended by No II para. 1 of the Ordinance of 28 Feb. 2007 (AS **2007** 821). Revised by No II para. 1 of the Ordinance of 14 Jan. 2009 (AS **2009** 401), of 10 Nov. 2010 (AS **2010** 5223), and of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

Xi



Irritant

[2] The symbols must be printed in black on an orange-yellow background.

1.2 Assignment of danger symbols and indications of danger

[1] Dangerous preparations must be labelled with the appropriate danger symbols and indications of danger according to their classification.

[2] If the manufacturer's classification requires more than one danger symbol for a preparation, the following applies:

a. if labelling with the T^+ or T danger symbol is required, the Xn, Xi and C symbols are optional;

b. if labelling with the C danger symbol is required, the Xn and Xi symbols are optional;

c. if labelling with the E danger symbol is required, the F, F^+ and O symbols are optional;

d. if labelling with the Xn danger symbol is required, the Xi symbol is optional.

2 Special Risks

2.1 R-phrases

R 1 Explosive when dry.

R 2 Risk of explosion by shock, friction, fire or other sources of ignition.

R 3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.

R 4 Forms very sensitive explosive metallic compounds.

R 5 Heating may cause an explosion.

R 6 Explosive with or without contact with air.

R 7 May cause fire.

R 8 Contact with combustible material may cause fire.

R 9 Explosive when mixed with combustible material.

R 10 Flammable.

R 11 Highly flammable.

R 12 Extremely flammable.
R 14 Reacts violently with water.
R 15 Contact with water liberates extremely flammable gases.
R 16 Explosive when mixed with oxidising substances.
R 17 Spontaneously flammable in air.
R 18 In use, may form flammable/explosive vapour-air mixture.
R 19 May form explosive peroxides.
R 20 Harmful by inhalation.
R 21 Harmful in contact with skin.
R 22 Harmful if swallowed.
R 23 Toxic by inhalation.
R 24 Toxic in contact with skin.
R 25 Toxic if swallowed.
R 26 Very toxic by inhalation.
R 27 Very toxic in contact with skin.
R 28 Very toxic if swallowed.
R 29 Contact with water liberates toxic gas.
R 30 Can become highly flammable in use.
R 31 Contact with acids liberates toxic gas.
R 32 Contact with acids liberates very toxic gas.
R 33 Danger of cumulative effects.
R 34 Causes burns.
R 35 Causes severe burns.
R 36 Irritating to eyes.
R 37 Irritating to respiratory system.
R 38 Irritating to skin.
R 39 Danger of very serious irreversible effects.
R 40 Limited evidence of a carcinogenic effect.
R 41 Risk of serious damage to eyes.
R 42 May cause sensitisation by inhalation.
R 43 May cause sensitisation by skin contact.
R 44 Risk of explosion if heated under confinement.
R 45 May cause cancer.
R 46 May cause heritable genetic damage.

R 48 Danger of serious damage to health by prolonged exposure.
R 49 May cause cancer by inhalation.
R 50 Very toxic to aquatic organisms.
R 51 Toxic to aquatic organisms.
R 52 Harmful to aquatic organisms.
R 53 May cause long-term adverse effects in the aquatic environment.
R 54 Toxic to flora.
R 55 Toxic to fauna.
R 56 Toxic to soil organisms.
R 57 Toxic to bees.
R 58 May cause long-term adverse effects in the environment.
R 59 Dangerous for the ozone layer.
R 60 May impair fertility.
R 61 May cause harm to the unborn child.
R 62 Possible risk of impaired fertility.
R 63 Possible risk of harm to the unborn child.
R 64 May cause harm to breastfed babies.
R 65 Harmful: may cause lung damage if swallowed.
R 66 Repeated exposure may cause skin dryness or cracking.
R 67 Vapours may cause drowsiness and dizziness.
R 68 Possible risk of irreversible effects.

2.2 Combined R-phrases

R 14/15 Reacts violently with water, liberating extremely flammable gases.
R 15/29 Contact with water liberates toxic, extremely flammable gases.
R 20/21 Harmful by inhalation and in contact with skin.
R 20/22 Harmful by inhalation and if swallowed.
R 20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R 21/22 Harmful in contact with skin and if swallowed.
R 23/24 Toxic by inhalation and in contact with skin.
R 23/25 Toxic by inhalation and if swallowed.
R 23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
R 24/25 Toxic in contact with skin and if swallowed.
R 26/27 Very toxic by inhalation and in contact with skin.

R 26/28	Very toxic by inhalation and if swallowed.
R 26/27/28	Very toxic by inhalation, in contact with skin and if swallowed.
R 27/28	Very toxic in contact with skin and if swallowed.
R 36/37	Irritating to eyes and respiratory system.
R 36/38	Irritating to eyes and skin.
R 36/37/38	Irritating to eyes, respiratory system and skin.
R 37/38	Irritating to respiratory system and skin.
R 39/23	Toxic: danger of very serious irreversible effects through inhalation.
R 39/24	Toxic: danger of very serious irreversible effects in contact with skin.
R 39/25	Toxic: danger of very serious irreversible effects if swallowed.
R 39/23/24	Toxic: danger of very serious irreversible effects through inhalation and in contact with skin.
R 39/23/25	Toxic: danger of very serious irreversible effects through inhalation and if swallowed.
R 39/24/25	Toxic: danger of very serious irreversible effects in contact with skin and if swallowed.
R 39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R 39/26	Very toxic: danger of very serious irreversible effects through inhalation.
R 39/27	Very toxic: danger of very serious irreversible effects in contact with skin.
R 39/28	Very toxic: danger of very serious irreversible effects if swallowed.
R 39/26/27	Very toxic: danger of very serious irreversible effects through inhalation and in contact with skin.
R 39/26/28	Very toxic: danger of very serious irreversible effects through inhalation and if swallowed.
R 39/27/28	Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed.
R 39/26/27/28	Very toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R 42/43	May cause sensitisation by inhalation and skin contact.
R 48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation.
R 48/21	Harmful: danger of serious damage to health by prolonged exposure in contact with skin.

R 48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R 48/20/21	Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.
R 48/20/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R 48/21/22	Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed.
R 48/20/21/22	Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
R 48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation.
R 48/24	Toxic: danger of serious damage to health by prolonged exposure in contact with skin.
R 48/25	Toxic: danger of serious damage to health by prolonged exposure if swallowed.
R 48/23/24	Toxic: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.
R 48/23/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed.
R 48/24/25	Toxic: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed.
R 48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
R 50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 68/20	Harmful: possible risk of irreversible effects through inhalation.
R 68/21	Harmful: possible risk of irreversible effects in contact with skin.
R 68/22	Harmful: possible risk of irreversible effects if swallowed.
R 68/20/21	Harmful: possible risk of irreversible effects through inhalation and in contact with skin.
R 68/20/22	Harmful: possible risk of irreversible effects through inhalation and if swallowed.
R 68/21/22	Harmful: possible risk of irreversible effects in contact with skin and if swallowed.

R 68/20/21/22 Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed.

2.3 Assignment of R-phrases

[1] Dangerous preparations must be labelled with the appropriate R-phrases according to their classification.

[2] As a general rule, no more than six R-phrases are to be used. However, each dangerous property of a classified preparation must be indicated by at least one R-phrase drawing attention to the principal hazard. Combined R-phrases are regarded as single R-phrases.

2.4 Choice of R-phrases

[1] …

[2] R-phrases must be assigned according to the following criteria and priorities:

a. Dangers to health:
   1. R-phrases corresponding to the category of danger illustrated by a symbol. In certain cases the R-phrases must be adopted according to the tables in Part B of Annex II to Directive 1999/45/EC. More specifically, the R-phrases of the constituents which are responsible for the assignment of the preparation to a danger category must appear on the label,
   2. R-phrases corresponding to other categories of danger which have been attributed to the constituents but which are not illustrated by a symbol;

b. Dangers arising from physicochemical properties:
   1. R-phrases corresponding to the category of danger illustrated by a symbol. More specifically, the R-phrases of the constituents which are responsible for the assignment of the preparation to a danger category must appear on the label,
   2. R-phrases corresponding to other categories of danger which have been attributed to the constituents but which are not illustrated by a symbol;
   3. The R-phrases R 11 and R 12 need not be indicated where they repeat the wording of the indication of danger used with a symbol;

c. Dangers for the environment:
   1. R-phrases corresponding to the category “dangerous for the environment”,
   2. Where the R-phrase R 50 has been assigned in addition to a combined R-phrase R 51/53 or R 52/53 or to the R-phrase R 53 alone, the combined R-phrase R 50/53 must be used.

2.5 Exemptions

[1] …

[2] It is not necessary to indicate the appropriate R-phrases for preparations that are placed on the market in packages containing not more than 125 ml and which:

a. are classified as highly flammable, oxidising or irritant, without the R-phrase "Risk of serious damage to eyes" (R 41); or

b. are classified as dangerous for the environment and assigned the N symbol.

[3] When the labelling includes the symbols F or F^+, the R-phrases R 11 or R 12 do not have to be indicated.

3 Safety Advice

3.1 S-phrases

S 1 Keep locked up.

S 2 Keep out of the reach of children.

S 3 Keep in a cool place.

S 4 Keep away from living quarters.

S 5 Keep contents under… (appropriate liquid to be specified by the manufacturer).

S 6 Keep contents under… (inert gas to be specified by the manufacturer).

S 7 Keep container tightly closed.

S 8 Keep container dry.

S 9 Keep container in a well-ventilated place.

S 12 Do not keep the container sealed.

S 13 Keep away from food, drink and animal feedingstuffs.

S 14 Keep away from… (incompatible materials to be indicated by the manufacturer).

S 15 Keep away from heat.

S 16 Keep away from sources of ignition – No smoking.

S 17 Keep away from combustible material.

S 18 Handle and open container with care.

S 20 When using do not eat or drink.

S 21 When using do not smoke.

S 22 Do not breathe dust.

S 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).

S 24 Avoid contact with skin.

S 25 Avoid contact with eyes.

S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 27 Take off immediately all contaminated clothing.

S 28 After contact with skin, wash immediately with plenty of… (to be specified by the manufacturer).

S 29 Do not empty into drains.

S 30 Never add water to this product.

S 33 Take precautionary measures against static discharges.

S 35 This material and its container must be disposed of in a safe way.

S 36 Wear suitable protective clothing.

S 37 Wear suitable gloves.

S 38 In case of insufficient ventilation, wear suitable respiratory equipment.

S 39 Wear eye/face protection.

S 40 To clean the floor and all objects contaminated by this material, use… (to be specified by the manufacturer).

S 41 In case of fire and/or explosion do not breathe fumes.

S 42 During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer).

S 43 In case of fire, use… (type of fire-fighting equipment to be specified by the manufacturer. If water increases the risk, add: "Never use water").

S 45 In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible).

S 46 If swallowed, seek medical advice immediately and show this container or label.

S 47 Keep at temperature not exceeding… °C (to be specified by the manufacturer).

S 48 Keep wet with… (appropriate material to be specified by the manufacturer).

S 49 Keep only in the original container.

S 50 Do not mix with… (to be specified by the manufacturer).

S 51 Use only in well-ventilated areas.

S 52 Not recommended for interior use on large surface areas.

S 53 Avoid exposure – obtain special instructions before use.

S 56 Dispose of this material and its container at hazardous or special waste collection point.

S 57 Use appropriate containment to avoid environmental contamination.

S 59 Refer to manufacturer/supplier for information on recovery/recycling.

S 60 This material and its container must be disposed of as hazardous waste.

S 61 Avoid release to the environment. Refer to special instructions/safety data sheet.

S 62 If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.

S 63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

S 64 If swallowed, rinse mouth with water (only if the person is conscious).

3.2 Combined S-phrases

S 1/2	Keep locked up and out of the reach of children.
S 3/7	Keep container tightly closed in a cool place.
S 3/9/14	Keep in a cool, well-ventilated place away from… (incompatible materials to be indicated by the manufacturer).
S 3/9/14/49	Keep only in the original container in a cool, well-ventilated place away from… (incompatible materials to be indicated by the manufacturer).
S 3/9/49	Keep only in the original container in a cool, well-ventilated place.
S 3/14	Keep in a cool place away from… (incompatible materials to be indicated by the manufacturer).
S 7/8	Keep container tightly closed and dry.
S 7/9	Keep container tightly closed and in a well-ventilated place.
S 7/47	Keep container tightly closed and at temperature not exceeding… °C (to be specified by the manufacturer).
S 20/21	When using do not eat, drink or smoke.
S 24/25	Avoid contact with skin and eyes.
S 27/28	After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of… (to be specified by the manufacturer).
S 29/35	Do not empty into drains; waste and containers must be disposed of in a safe way.
S 29/56	Do not empty into drains; dispose of this material and its container at hazardous or special waste collection point.
S 36/37	Wear suitable protective clothing and gloves.
S 36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S 36/39	Wear suitable protective clothing and eye/face protection.

S 37/39 Wear suitable protective clothing, gloves and eye/face protection.

S 47/49 Keep only in the original container at temperature not exceeding … °C (to be specified by the manufacturer).

3.3 Assignment of S-phrases

[1] Dangerous preparations must be labelled with the appropriate S-phrases according to their classification. The choice of S-phrases is based on Section 6 of Annex VI to Directive 67/548/EEC[233].

[2] As a general rule, no more than six S-phrases are to be used. Combined S-phrases are regarded as single phrases.

[3] An S-phrase concerning disposal of the preparation must be used, unless it is clear that disposal of the preparation or its container does not present a danger for human health or the environment.

[4] With regard to dangerous preparations that are sold to the general public, the following applies:

a. The S-phrases S 1, S 2 and S 45 are obligatory for all very toxic, toxic and corrosive preparations.

b. The S-phrase S 2 is obligatory for all dangerous preparations other than those referred to under letter a, except for those that are only classified as dangerous to the environment.

c. The S-phrase S 46 is obligatory for all preparations referred to under letter b unless there is no reason to fear any danger from swallowing, particularly by children.

[5] The choice of S-phrases must take account of the intended use and the foreseeable conditions of use.

[6] S-phrases must be chosen in such a way as to avoid any redundancy or ambiguity.

[7] If, for technical reasons, the S-phrases cannot appear on the label or on the packaging, they may be supplied separately as written information.

3.4 Exemptions

[1] …

[2] It is not necessary to indicate the appropriate S-phrases for preparations that are placed on the market in packages containing not more than 125 ml and which:

a. are classified as highly flammable, flammable, oxidising or irritant, without the R-phrase “Risk of serious damage to eyes” (R 41); or

b. are classified as dangerous to the environment.

233 See footnote to Art. 3 let. b.

4 Declaration of Dangerous Substances in Preparations

[1] As a general rule, no more than four dangerous substances responsible for the main dangerous properties of a preparation need to be indicated.

[2] In all cases, it is necessary to indicate dangerous substances that have led to the preparation being classified as follows:

a. carcinogenic;

b. mutagenic;

c. toxic to reproduction;

d. very toxic, toxic or harmful, when the effects of a single exposure are not lethal;

e. toxic or harmful, when the effects of repeated or prolonged exposure are severe;

f. sensitising.

[3] Without prejudice to paragraph 2, it is not necessary to indicate dangerous substances that have led to the preparation being classified as follows:

a. explosive;

b. oxidising;

c. extremely flammable;

d. highly flammable;

e. flammable;

f. irritant;

g. dangerous to the environment.

[4] As regards preparations assigned the danger symbol T^+, T or Xn, only those substances with the symbol T^+, T or Xn need to be taken into account, subject to paragraph 3, whose concentration is equal to or exceeds the following lowest limit (Xn limit):

a. the Xn limit established during official classification;

b. if no limit has been established as defined in paragraph a: the Xn limit according to Part B of Annex II to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999[234] on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (Directive 1999/45/EC).

[5] As regards preparations assigned the danger symbol C, only those substances with the symbol C need to be taken into account, subject to paragraph 3, whose concentration is equal to or exceeds the following lowest limit (Xi limit):

234 OJ L 200, 30.7.1999, p. 1, last amended by Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).

a. the limit established during official classification;

b. the Xi limit according to Part B of Annex II to Directive 1999/45/EC.

5 Provisions relating to Preparations with Special Risks

5.1 Cyanoacrylate-based adhesives

[1] Cyanoacrylate-based adhesives must be labelled as follows: "Cyanoacrylate. Danger. Bonds skin and eyes in seconds. Keep out of the reach of children."

[2] Appropriate advice on safety must accompany the package.

5.2 Preparations containing isocyanates

Preparations containing isocyanates (as monomers, oligomers, prepolymers, etc. or as mixtures thereof) must be labelled as follows: "Contains isocyanates. See information supplied by the manufacturer."

5.3 Preparations containing epoxy constituents with an average molecular weight ≤ 700

Preparations containing epoxy constituents with an average molecular weight ≤ 700 must be labelled as follows: "Contains epoxy constituents. See information supplied by the manufacturer."

5.4 Preparations which contain active chlorine

Preparations containing more than 1% of active chlorine which are sold to the general public must be labelled as follows: "Warning! Do not use together with other products. May release dangerous gases (chlorine)."

5.5 Preparations containing cadmium (alloys) and intended to be used for brazing or soldering

Preparations containing cadmium (alloys) and intended to be used for brazing or soldering must be labelled as follows: "Warning! Contains cadmium. Dangerous fumes are formed during use. See information supplied by the manufacturer. Comply with the safety instructions."

5.6 Preparations available as aerosols

[1] Aerosol dispensers not covered by the Foodstuffs Act of 9 October 1992[235] are subject both to the provisions of this Ordinance and to Articles 1, 2, 8 paragraph 1*a*,

[235] SR **817.0**

the introductory provision of point 2 and points 2.2 and 2.3 of the Annex to Directive 75/324/EEC[236].

[2] In the case of aerosol dispensers not deemed to be dangerous under Article 3 of this Ordinance, the manufacturer's name and address must be indicated. If the aerosol dispenser is imported from an EEA member state, the manufacturer's name may be replaced by the name of the person responsible for placing it on the market in the EEA, as specified in Article 10 point 2.2 of Directive 1999/45/EC[237].

5.7 Preparations not classified as sensitising but containing at least one substance classified as sensitising

Preparations not classified as sensitising but containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0.1% or in a concentration equal to or greater than that specified for the substance in the official classification (Art. 9) must be labelled as follows: “Contains (name of sensitising substance). May produce an allergic reaction.”

5.8 Liquid preparations containing halogenated hydrocarbons

Preparations which show no flashpoint or a flashpoint higher than 55°C and contain a halogenated hydrocarbon and more than 5% flammable or highly flammable substances must be labelled as follows, as appropriate: “Can become flammable in use” or “Can become highly flammable in use”.

5.9 Preparations not classified as dangerous but containing at least one dangerous substance and not sold to the general public

Preparations not classified as dangerous but containing at least one dangerous substance and which are not sold to the general public must be labelled as follows: “Safety data sheet available for professional users on request”.

5.10 Preparations containing a substance assigned R-phrase R 67

[1] Preparations containing a substance assigned R-phrase R 67 in a total concentration equal to or greater than 15% must be labelled with R-phrase R 67.

[2] The labelling specified in paragraph 1 is not required if:

a. R-phrase R 20, R 23, R 26, R 68/20, R 39/23 or R 39/26 is assigned to the preparation; or

b. the package does not contain more than 125 ml.

236 See footnote to Art. 37 para. 4.
237 See footnote to Art. 12 para. 1.

5.11 Dangerous preparations available to the general public

[1] Dangerous preparations sold to the general public must be labelled with S-phrases in accordance with number 3.3.

[2] Where it is physically impossible to give instructions on the package itself, preparations classified as toxic (T) or corrosive (C) must be accompanied by precise and easily understandable instructions for use including, if applicable, instructions for the destruction of the empty package. The instructions must be written in at least two official languages.

5.12 Dangerous preparations intended for use by spraying

Dangerous preparations intended for use by spraying must be labelled with S-phrase S 23, accompanied by S-phrases S 38 or S 51.

5.13 Preparations containing a substance assigned R-phrase R 33

When a preparation contains a substance assigned R-phrase R 33, it must be labelled with R-phrase R 33 if this substance is present in a concentration equal to or higher than 1%, unless different concentration limits are set in the official classification (Art. 9).

5.14 Preparations containing a substance assigned R-phrase R 64

When a preparation contains a substance assigned R-phrase R 64, it must be labelled with R-phrase R 64 if this substance is present in a concentration equal to or higher than 1%, unless different concentration limits are set in the official classification (Art. 9).

6 Label

[1] The label must be affixed to the packaging in such a way that the information can be read horizontally when the package is set down normally.

[2] The dimensions of the label must be as follows:

Capacity of the package	Dimensions (in mm)
not exceeding 3 litres	if possible at least 52×74
greater than 3 litres but not exceeding 50 litres	at least 74×105
greater than 50 litres but not exceeding 500 litres	at least 105×148
greater than 500 litres	at least 148×210

[3] The label must contain only the information stipulated in this Ordinance for labelling, as well as any additional information regarding hygiene and safety which may be applicable.

[4] Each symbol must cover at least one-tenth of the surface area of the label but must not be less than 1 cm^2.

[5] A label is not required if the information specified in Articles 39–46 is clearly shown on each package.

[6] The colour and presentation of the label or, in the case of paragraph 5, of the package must be such that the danger symbol and its background stand out clearly from it.

[7] In the case of mobile gas cylinders, the requirements relating to labelling are deemed to have been met if these cylinders comply with the relevant stipulations in Annex VI to Directive 67/548/EEC.

7 Optional Labelling

7.1 Indications of dangers for the environment

Number	Pictogram	Examples of wording
7.1.1	 Toxic to bees	Do not spray before or during flowering. Do not treat plants affected by greenfly. Take care when plants nearby are in full bloom or are interspersed with flowering weeds. Do not use in wind.
7.1.2	 Dangerous for groundwater	Use prohibited in groundwater protection zones S (S 1, S 2 and S 3) of drinking water wells. Do not spread on fallow or temporarily fallow land. Do not use in karstic regions, or on porous soils. Do not use on railways. Storage prohibited in groundwater protection zones S (S 1, S 2 and S 3) of drinking water wells.

7.2 Information on protective measures

Number	Pictogram	Examples of wording
7.2.1	 Domestic waste	May be disposed of with domestic waste.
7.2.2	 Hazardous waste	Hand in to …(company) as hazardous waste. Return to point of sale as hazardous waste. Return to toxic waste collection point as hazardous waste. Hand in to used oil collection point as hazardous waste. *Note: the label must clearly indicate the recommended method of disposal.*
7.2.3	 Not to be disposed of via drains	Do not empty into the sink or the toilet, but dispose of with domestic waste. Do not empty into the sink or the toilet, but return to point of sale or waste collection point. *Note: the label must clearly indicate the recommended method of disposal.*

Annex 2[238]
(Art. 53)

238 Repealed by No. II para. 2 of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).

Annex 3[239]
(Art. 16*a*, Art. 17 para. 2, Art. 18 para. 2 let. b and Art. 60 para. 1)

Technical Dossier

General Provisions

1 The information in the technical dossier may be submitted in a form approved by the European Chemicals Agency. In this case, certain expressions may differ from those used in this Annex.

2 The information required under numbers 6–9 depends on the decisive substance quantity in accordance with Article 16*a*.

1 General Notifier Information

1 The notifier's identity must be provided, specifically:

a. name, address, telephone number and e-mail address;

b. a contact person;

c. if applicable, the location of the notifier's production sites;

2 In addition, if the notifier is the sole representative, the following information is required:

a. foreign manufacturer's name and address;

b. location of the production sites;

c. authorisation from the foreign manufacturer stating that it appointed the notifier as its sole representative;

d. names and addresses of the importers represented;

e. the quantities of a substance that each importer intends to import annually.

2 Identification of the Substance

The following information on the substance must be provided:

a. data specified in Section 2 of Annex VI to the REACH Regulation[240];

b. in the case of nanomaterials: data on the composition and, where available, the surface coating and surface functionalisation.

239 Inserted by No II para. 3 of the Ordinance of 14 Jan. 2009 (AS **2009** 401 1135). Revised by No II para. 1 of the Ordinance of 10 Nov. 2010 (AS **2010** 5223) and of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).

240 See footnote to Art. 2 para. 4.

3 Information on Manufacture and Use

The following information must be provided:

a. the estimated overall quantity to be placed on the market by the notifier in the calendar year of the notification;

b. the quantities for the notifier's own use;

c. the form or physical state in which the substance is made available;

d. a brief description of the identified use(s).

e. information on waste quantities and composition of waste resulting from manufacture of the substance, the use in objects and identified uses;

f. uses advised against (Section 1.2 of the safety data sheet).

4 Classification and Labelling

The following must be indicated:

a. the classification of the substance according to Article 8 paragraph 1 of this Ordinance for all hazard classes and categories of the CLP Regulation[241]; if no classification has been given for a hazard class or differentiation of a hazard class, the reasons are to be provided;

b. the labelling of the substance in accordance with Article 34*b*;

c. any specific concentration limits resulting from the application of Article 10 of the CLP Regulation.

5 Guidance on Safe Use

The following information, which must be consistent with that in the safety data sheet, where such a safety data sheet is required in accordance with Article 52, must be stated:

a. first-aid measures (safety data sheet, No. 4);

b. fire-fighting measures (safety data sheet, No. 5);

c. accidental release measures (safety data sheet, No. 6);

d. handling and storage (safety data sheet, No. 7);

e. transport information (safety data sheet, No. 14);

f. exposure controls/personal protection (safety data sheet, No. 8);

g. stability and reactivity (safety data sheet, No. 10);

h. disposal considerations. Information on recycling and methods of disposal for industry and for the public (safety data sheet, No. 13).

241 See footnote to Art. 2 para. 4.

6 Information on Exposure (1–10 tonnes per year)

For substances with a decisive quantity according to Article 16*a* of between 1 and 10 tonnes per year, the following information on exposure must be provided:

a. main use categories:
   1. industrial use,
   2. professional use,
   3. consumer use;

b. specification for industrial and professional use:
   1. use in a closed system,
   2. use resulting in inclusion into or onto matrix,
   3. non-dispersive use,
   4 dispersive use;

c. significant routes of exposure:
   1. human exposure: oral, dermal and inhalatory,
   2. environmental exposure: water, air, solid waste and soil,
   3. pattern of exposure: accidental/infrequent, occasional or continuous/ frequent.

7 Information on Physicochemical Properties

The following information must be provided:

a. for decisive quantities according to Article 16*a* of 1 tonne per year or more:
   1. robust study summaries with regard to the information specified in Section 7 of Annex VII to the REACH Regulation[242],
   2. in the case of nanomaterials: the particle form and mean particle size and, where available, the number size distribution, specific surface area by volume and aggregation status;

b. for decisive quantities according to Article 16*a* of 100 tonnes per year or more: in addition to the information required by letter a, robust study summaries with regard to the information specified in Section 7 of Annex IX to the REACH Regulation.

8 Toxicological Information

Robust study summaries must be provided with regard to the following information:

a. for quantities of 1 tonne per year or more: the information specified in Section 8 of Annex VII to the REACH Regulation[243];

242 See footnote to Art. 2 para. 4.
243 See footnote to Art. 2 para. 4.

b. for quantities of 10 tonnes per year or more: in addition to the information required by letter a, the information specified in Section 8 of Annex VIII to the REACH Regulation;

c. for quantities of 100 tonnes per year or more: in addition to the information required by letters a and b, the information specified in Section 8 of Annex IX to the REACH Regulation;

d for quantities of 1,000 tonnes per year or more: in addition to the information required by letters a–c, the information specified in Section 8 of Annex X to the REACH Regulation.

9 Exotoxicological Information

Robust study summaries must be provided with regard to the following information:

a. for quantities of 1 tonne per year or more: the information specified in Section 9 of Annex VII to the REACH Regulation[244];

b. for quantities of 10 tonnes per year or more: in addition to the information required by letter a, the information specified in Section 9 of Annex VIII to the REACH Regulation;

c. for quantities of 100 tonnes per year or more: in addition to the information required by letters a and b, the information specified in Section 9 of Annex IX to the REACH Regulation;

d for quantities of 1,000 tonnes per year or more: in addition to the information required by letters a–c, the information specified in Section 9 of Annex X to the REACH Regulation.

10 Omission of certain Tests

Certain tests specified in numbers 7–9 may be omitted if, according to the criteria specified in Annex XI to the REACH Regulation[245]:

a. testing does not appear scientifically necessary;

b. testing is technically not possible;

c. the exposure assessment makes it possible for certain tests to be omitted.

244 See footnote to Art. 2 para. 4.
245 See footnote to Art. 2 para. 4.

Annex 4[246]

246 Inserted by No II para. 3 of the Ordinance of 14 Jan. 2009 (AS **2009** 401). Repealed by No. II para. 2 of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).

Annex 5[247]
(Art. 2 para. 4)

Correspondences between expressions, legislation and individual provisions

For the correct interpretation of the REACH Regulation[248] and the CLP Regulation[249], to which reference is made in this Ordinance, the following correspondences between expressions, legislation and individual provisions apply:

1 Equivalent expressions

Terms used in the EU	Terms used in Switzerland
Manufacturer, supplier, importer, downstream user	Manufacturer as defined by Article 2 paragraph 1 letter c
Placing on the market	Placing on the market as defined by Article 4 paragraph 1 letter i ChemA
Mixture	Preparation
Article	Object
Intermediate	Intermediate as defined by Article 2 paragraph 2 letter d
Where a chemical safety report is required	If exposure scenarios must be attached to the safety data sheet
Official advisory body	Swiss Toxicological Information Centre (Art. 91)

2 Swiss provisions corresponding to EU legislation cited in the REACH Regulation and in the CLP Regulation and to individual EU provisions

EU legislation and individual provisions	Swiss legislation and individual provisions
Directive 86/609/EEC	Animal Protection Act of 16 December 2005[250]
Directive 98/8/EC	Biocidal Products Ordinance of 18 May 2005[251]

247 Inserted by No. II para. 3 of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
248 See footnote to Art. 2 para. 4.
249 See footnote to Art. 2 para. 4.
250 SR **455**

EU legislation and individual provisions	Swiss legislation and individual provisions
Directive 91/414/EEC	Plant Protection Products Ordinance of 12 May 2010[252]
Rules on the transport of dangerous goods	Regulations concerning transport by post, rail, road, air, water and pipelines
Decision 95/320/EC	Art. 50 para. 3 of the Ordinance of 19 December 1983[253] on Accident Prevention
Directive 98/24/EC	Legislation on the protection of workers
Directive 2004/37/EC	Legislation on the protection of workers
National occupational exposure limit values	List of occupational exposure limit values published by SUVA[254]
Directive 89/686/EEC	Ordinance of 19 May 2010[255] on Product Safety
Directive 2008/98/EC	Technical Ordinance of 10 December 1990[256] on Wastes and Ordinance of 22 June 2005[257] on the Movement of Wastes
Regulation (EC) No 2037/2000	Annex 1.4 ORRChem[258]
Regulation (EC) No 850/2004	Annexes 1.1, 1.9 and 1.16 ORRChem
Regulation (EC) No 689/2008	PIC Ordinance of 10 November 2004[259]
Directive 96/82/EC	Major Accidents Ordinance of 27 February 1991[260]
Art. 13 of the REACH Regulation[261]	Art. 34 para. 2
Art. 31 of the REACH Regulation	Art. 53
Art. 59 of the REACH Regulation	Annex 7
Art. 24 of the CLP Regulation[262]	Art. 43

251 SR **813.12**
252 SR **916.161**
253 SR **832.30**
254 The list of Swiss occupational exposure limit values is available online at www.suva.ch/waswo/1903.d (German) and www.suva.ch/waswo/1903.f (French)
255 SR **930.111**
256 SR **814.600**
257 SR **814.610**
258 SR **814.81**
259 SR **814.82**
260 SR **814.012**
261 See footnote to Art. 2 para. 4.
262 See footnote to Art. 2 para. 4.

Annex 6[263]
(Art. 76)

Substances and preparations in Groups 1 and 2

1 Substances and preparations labelled in accordance with the CLP Regulation[264]

1.1 Group 1

a.	 in conjunction with	(H300)[265]: Fatal if swallowed, or H310: Fatal in contact with skin, or H330: Fatal if inhaled, or combinations of the above hazard statements
b.		
c.	Substances and preparations labelled as follows in accordance with Annex 1.10 ORRChem:  in conjunction with	H340: May cause genetic defects, or H350: May (*if inhaled*) cause cancer, or H360: May damage fertility or the unborn child

263 Inserted by No. II para. 3 of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103). Revised by Annex 11 No 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
264 See footnote to Art. 2 para. 4.
265 Need not appear in the labelling (used for codification of hazard statements).

1.2 Group 2

a.	 in conjunction with	H301: Toxic if swallowed, or H311: Toxic in contact with skin, or H331: Toxic if inhaled, or combinations of the above hazard statements
b.	 in conjunction with	H370: Causes damage to organs, or H372: Causes damage to organs through prolonged or repeated exposure
c.	 in conjunction with	H314: Causes severe skin burns and eye damage
d.	Containers with a content of more than 1 kg labelled as follows:  in conjunction with	H410: Very toxic to aquatic life with long lasting effects
e.	 in conjunction with	H250: Catches fire spontaneously if exposed to air, or H260: In contact with water releases flammable gases which may ignite spontaneously, or H261: In contact with water releases flammable gases
f.		EUH006: Explosive with or without contact with air, or EUH019: May form explosive peroxides, or EUH029: Contact with water liberates toxic gas, or EUH032: Contact with acids liberates very toxic gas
g.	Substances and preparations that can release chlorine gas, labelled as follows:	EUH031: Contact with acids liberates toxic gas

2 Substances and preparations not yet labelled in accordance with the CLP Regulation[266]

2.1 Group 1

a.	 in conjunction with	R28: Very toxic if swallowed, or R27: Very toxic in contact with skin, or R26: Very toxic by inhalation, or combinations of the above R phrases
b.		
c.	Substances and preparations labelled as follows in accordance with Annex 1.10 ORRChem:  in conjunction with	R46: May cause heritable genetic damage, or R45: May cause cancer, or R49: May cause cancer by inhalation, or R60: May impair fertility, or R61: May cause harm to the unborn child

2.2 Group 2

a.	 in conjunction with	R25: Toxic if swallowed, or R24: Toxic in contact with skin, or R23: Toxic by inhalation, or combinations of the above R phrases
b.	 in conjunction with	R39: Danger of very serious irreversible effects, or R48: Danger of serious damage to health by prolonged exposure
c.	 in conjunction with	R35: Causes severe burns, or R34: Causes burns

266 See footnote to Art. 2 para. 4.

d.	Containers with a content of more than 1 kg labelled as follows:  in conjunction with	R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
e.	 in conjunction with	R17: Spontaneously flammable in air, or R15: Contact with water liberates extremely flammable gases
f.		R6: Explosive with or without contact with air, or R19: May form explosive peroxides, or R29: Contact with water liberates toxic gas, or R32: Contact with acids liberates very toxic gas
g.	Substances and preparations that can release chlorine gas, labelled as follows:	EUH031: Contact with acids liberates toxic gas

List of substances of very high concern (candidate list)

This list was last revised on 1 September 2014 and contains 154 substances.

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
1,2,3-Trichloropropane		202-486-1	96-18-4	Carcinogenic and toxic for reproduction
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich		276-158-1	71888-89-6	Toxic for reproduction
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters		271-084-6	68515-42-4	Toxic for reproduction
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear		271-093-5	68515-50-4	Toxic for reproduction
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear		284-032-2	84777-06-0	Toxic for reproduction
1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)		203-977-3	112-49-2	Toxic for reproduction
1,2-dichloroethane		203-458-1	107-06-2	Carcinogenic
1,2-Diethoxyethane		211-076-1	629-14-1	Toxic for reproduction
1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)		203-794-9	110-71-4	Toxic for reproduction
1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)		219-514-3	2451-62-9	Mutagenic
1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)		423-400-0	59653-74-6	Mutagenic
1-bromopropane (n-propyl bromide)		203-445-0	106-94-5	Toxic for reproduction
1-Methyl-2-pyrrolidone		212-828-1	872-50-4	Toxic for reproduction

267 Inserted by No. II para. 3 of the Ordinance of 7 Nov. 2012 (AS **2012** 6103). Amended by No I of the FOPH Ordinance of 17 Nov. 2014, in force since 1 Dec. 2014 (AS **2014** 3857)

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
2,2’-dichloro-4,4’-methylenedianiline		202-918-9	101-14-4	Carcinogenic
2,4-Dinitrotoluene		204-450-0	121-14-2	Carcinogenic
2-Ethoxyethanol		203-804-1	110-80-5	Toxic for reproduction
2-Ethoxyethyl acetate		203-839-2	111-15-9	Toxic for reproduction
2-Methoxyaniline; o-Anisidine		201-963-1	90-04-0	Carcinogenic
2-Methoxyethanol		203-713-7	109-86-4	Toxic for reproduction
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine		421-150-7	143860-04-2	Toxic for reproduction
4-(1,1,3,3-tetramethylbutyl)phenol		205-426-2	140-66-9	Equivalent level of concern having probable serious effects to the environment
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	covering well-defined substances and UVCB substances, polymers and homologues			Equivalent level of concern having probable serious effects to the environment
4,4’-Diaminodiphenylmethane (MDA)		202-974-4	101-77-9	Carcinogenic
4,4’-bis(dimethylamino)-4’’-(methylamino)trityl alcohol	with ≥ 0.1 % of Michler’s ketone (EC No. 202-027-5) or Michler’s base (EC No. 202-959-2)	209-218-2	561-41-1	Carcinogenic
4,4’-bis(dimethylamino)benzophenone (Michler’s ketone)		202-027-5	90-94-8	Carcinogenic
[4-[4,4’-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)	with ≥ 0.1 % of Michler’s ketone (EC No. 202-027-5) or Michler’s base (EC No. 202-959-2)	208-953-6	548-62-9	Carcinogenic
[4-[[4-anilino-1-naphthyl][4-(dimethylamino) phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)	with ≥ 0.1 % of Michler’s ketone (EC No. 202-027-5) or Michler’s base (EC No. 202-959-2)	19-943-6	2580-56-5	Carcinogenic
4,4’-methylenedi-o-toluidine		212-658-8	838-88-0	Carcinogenic
4,4’-oxydianiline and its salts		202-977-0	101-80-4	Carcinogenic
4-Aminoazobenzene		200-453-6	60-09-3	Carcinogenic

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
4-methyl-m-phenylenediamine (toluene-2,4-diamine)		202-453-1	95-80-7	Carcinogenic
4-Nonylphenol, branched and linear	substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof			Equivalent level of concern having probable serious effects to the environment
4-Nonylphenol, branched and linear, ethoxylated	substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]			Equivalent level of concern having probable serious effects to the environment
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)		201-329-4	81-15-2	vPvB
6-methoxy-m-toluidine (p-cresidine)		204-419-1	120-71-8	Carcinogenic
Acetic acid, lead salt, basic		257-175-3	51404-69-4	Toxic for reproduction
Acids generated from chromium trioxide and their oligomers. Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid.		231-801-5, 236-881-5	7738-94-5, 13530-68-2	Carcinogenic
Acrylamide		201-173-7	79-06-1	Carcinogenic and mutagenic
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)		287-476-5	85535-84-8	PBT and vPvB

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
Aluminosilicate Refractory Ceramic Fibres	are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al2O3 and SiO2 are present within the following concentration ranges:Al2O3: 43.5–47 % w/w, and SiO2: 49.5–53.5 % w/w, or Al2O3: 45.5–50.5 % w/w, and SiO2: 48.5–54 % w/w,b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm).	–	Extracted from Index no.: 650-017-00-8	Carcinogenic
Ammonium dichromate		232-143-1	7789-09-5	Carcinogenic, mutagenic and toxic for reproduction
Ammonium pentadecafluorooctanoate (APFO)		223-320-4	3825-26-1	Toxic for reproduction
Anthracene		204-371-1	120-12-7	PBT
Anthracene oil		292-602-7	90640-80-5	Carcinogenic[1], PBT and vPvB
Anthracene oil, anthracene paste		292-603-2	90640-81-6	Carcinogenic[2], mutagenic[3], PBT and vPvB
Anthracene oil, anthracene paste, anthracene fraction		295-275-9	91995-15-2	Carcinogenic[2], mutagenic[3], PBT and vPvB
Anthracene oil, anthracene paste,distn. lights		295-278-5	91995-17-4	Carcinogenic[2], mutagenic[3], PBT and vPvB

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
Anthracene oil, anthracene-low		292-604-8	90640-82-7	Carcinogenic[2], mutagenic[3], PBT and vPvB
Arsenic acid		231-901-9	7778-39-4	Carcinogenic
Benzyl butyl phthalate (BBP)		201-622-7	85-68-7	Toxic for reproduction
Biphenyl-4-ylamine		202-177-1	92-67-1	Carcinogenic
Bis (2-ethylhexyl)phthalate (DEHP)		204-211-0	117-81-7	Toxic for reproduction
Bis (2-methoxyethyl) ether		03-924-4	111-96-6	Toxic for reproduction
Bis (2-methoxyethyl) phthalate		204-212-6	117-82-8	Toxic for reproduction
Bis (pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE)		214-604-9	1163-19-5	PBT
Bis(tributyltin)oxide (TBTO)		200-268-0	56-35-9	PBT
Boric acid		233-139-2/ 234-343-4	10043-35-3/ 11113-50-1	Toxic for reproduction
Cadmium		231-152-8	7440-43-9	Carcinogenic
Cadmium chloride		233-296-7	10108-64-2	Carcinogenic, Mutagenic, Toxic for reproduction and Equivalent level of concern having probable serious effects to human health
Cadmium oxide		215-146-2	1306-19-0	Carcinogenic
Cadmium sulphide		215-147-8	1306-23-6	Carcinogenic
Calcium arsenate		231-904-5	7778-44-1	Carcinogenic
Chromium trioxide		215-607-8	1333-82-0	Carcinogenic and mutagenic
Cobalt dichloride		231-589-4	7646-79-9	Carcinogenic and toxic for reproduction
Cobalt(II) carbonate		208-169-4	513-79-1	Carcinogenic and toxic for reproduction

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
Cobalt(II) diacetate		200-755-8	71-48-7	Carcinogenic and toxic for reproduction
Cobalt(II) dinitrate		233-402-1	10141-05-6	Carcinogenic and toxic for reproduction
Cobalt(II) sulphate		233-334-2	10124-43-3	Carcinogenic and toxic for reproduction
Diarsenic pentaoxide		215-116-9	1303-28-2	Carcinogenic
Diarsenic trioxide		215-481-4	1327-53-3	Carcinogenic
Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))		204-650-8	123-77-3	Equivalent level of concern having probable serious effects to human health
Diboron trioxide		215-125-8	1303-86-2	Toxic for reproduction
Dibutyl phthalate (DBP)		201-557-4	84-74-2	Toxic for reproduction
Dibutyltin dichloride (DBTC)		211-670-0	683-18-1	Toxic for reproduction
Dichromium tris(chromate)		246-356-2	24613-89-6	Carcinogenic
Diethyl sulphate		200-589-6	64-67-5	Carcinogenic; Mutagenic
Dihexyl phthalate		201-559-5	84-75-3	Toxic for reproduction
Diisobutyl phthalate		201-553-2	84-69-5	Toxic for reproduction
Diisopentylphthalate		210-088-4	605-50-5	Toxic for reproduction
Dimethyl sulphate		201-058-1	77-78-1	Carcinogenic
Dinoseb (6-sec-butyl-2,4-dinitrophenol)		201-861-7	88-85-7	Toxic for reproduction
Dioxobis(stearato)trilead		235-702-8	12578-12-0	Toxic for reproduction
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)		209-358-4	573-58-0	Carcinogenic
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)		217-710-3	1937-37-7	Carcinogenic
Disodium tetraborate, anhydrous		215-540-4	1303-96-4/ 1330-43-4/ 12179-04-3	Toxic for reproduction

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
Dipentyl phthalate (DPP)		205-017-9	131-18-0	Toxic for reproduction
Fatty acids, C16-18, lead salts		292-966-7	91031-62-8	Toxic for reproduction
Formaldehyde, oligomeric reaction products with aniline		500-036-1	25214-70-4	Carcinogenic
Formamide		200-842-0	75-12-7	Toxic for reproduction
Furan		203-727-3	110-00-9	Carcinogenic
Henicosafluoroundecanoic acid		218-165-4	2058-94-8	vPvB
Heptacosafluorotetradecanoic acid		206-803-4	376-06-7	vPvB
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified:	Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	247-148-4 and 221-695-9	25637-99-4 3194-55-6 (134237-50-6) (134237-51-7) (134237-52-8)	PBT
Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4]	The individual isomers [2], [3] and [4] (including their cis- and trans-stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry	247-094-1, 243-072-0, 256-356-4, 260-566-1	25550-51-0, 9438-60-9, 48122-14-1, 7110-29-9	Equivalent level of concern having probable serious effects to human health
Hydrazine		206-114-9	302-01-2/ 7803-57-8	Carcinogenic
Imidazolidine-2-thione (2-imidazoline-2-thiol)		202-506-9	96-45-7	Toxic for reproduction
Lead bis(tetrafluoroborate)		237-486-0	13814-96-5	Toxic for reproduction
Lead chromate		231-846-0	7758-97-6	Carcinogenic and toxic for reproduction
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)		235-759-9	12656-85-8	Carcinogenic and toxic for reproduction
Lead cyanamidate		244-073-9	20837-86-9	Toxic for reproduction
Lead di(acetate)		206-104-4	301-04-2	Toxic for reproduction
Lead diazide, Lead azide		236-542-1	13424-46-9	Toxic for reproduction

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
Lead dinitrate		233-245-9	10099-74-8	Toxic for reproduction
Lead dipicrate		229-335-2	6477-64-1	Toxic for reproduction
Lead hydrogen arsenate		232-064-2	7784-40-9	Carcinogenic and toxic for reproduction
Lead monoxide (lead oxide)		215-267-0	1317-36-8	Toxic for reproduction
Lead oxide sulfate		234-853-7	12036-76-9	Toxic for reproduction
Lead styphnate		239-290-0	15245-44-0	Toxic for reproduction
Lead sulfochromate yellow (C.I. Pigment Yellow 34)		215-693-7	1344-37-2	Carcinogenic and toxic for reproduction
Lead titanium trioxide		235-038-9	12060-00-3	Toxic for reproduction
Lead titanium zirconium oxide		235-727-4	12626-81-2	Toxic for reproduction
Lead(II) bis(methanesulfonate)		401-750-5	17570-76-2	Toxic for reproduction
Methoxyacetic acid		210-894-6	625-45-6	Toxic for reproduction
Methyloxirane (Propylene oxide)		200-879-2	75-56-9	Carcinogenic; Mutagenic
N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)		202-959-2	101-61-1	Carcinogenic
N,N-dimethylacetamide		204-826-4	127-19-5	Toxic for reproduction
N,N-dimethylformamide		200-679-5	68-12-2	Toxic for reproduction
N-methylacetamide		201-182-6	79-16-3	Toxic for reproduction
N-pentyl-isopentylphthalate		–	776297-69-9	Toxic for reproduction
o-aminoazotoluene		202-591-2	97-56-3	Carcinogenic
Orange lead (lead tetroxide)		215-235-6	1314-41-6	Toxic for reproduction
o-Toluidine		202-429-0	95-53-4	Carcinogenic
Pentacosafluorotridecanoic acid		276-745-2	72629-94-8	vPvB
Pentadecafluorooctanoic acid (PFOA)		206-397-9	335-67-1	Toxic for reproduction
Pentalead tetraoxide sulphate		235-067-7	12065-90-6	Toxic for reproduction
Pentazinc chromate octahydroxide		256-418-0	49663-84-5	Carcinogenic

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
Phenolphthalein		201-004-7	77-09-8	Carcinogenic
[Phthalato(2-)]dioxotrilead		273-688-5	69011-06-9	Toxic for reproduction
Pitch, coal tar, high temp.		266-028-2	65996-93-2	Carcinogenic, PBT and vPvB
Potassium chromate		232-140-5	7789-00-6	Carcinogenic and mutagenic
Potassium dichromate		231-906-6	7778-50-9	Carcinogenic, mutagenic and toxic for reproduction
Potassium hydroxyoctaoxodizincatedichromate		234-329-8	11103-86-9	Carcinogenic
Pyrochlore, antimony lead yellow		232-382-1	8012-00-8	Toxic for reproduction
Silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped	with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD); the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008	272-271-5	68784-75-8	Toxic for reproduction
Silicic acid, lead salt		234-363-3	11120-22-2	Toxic for reproduction
Sodium chromate		231-889-5	7775-11-3	Carcinogenic, mutagenic and toxic for reproduction
Sodium dichromate		234-190-3	7789-12-0/ 10588-01-9	Carcinogenic, mutagenic and toxic for reproduction
Sodium perborate; perboric acid, sodium; salt		239-172-9; 234-390-0	–	Toxic for reproduction
Sodium peroxometaborate		231-556-4	7632-04-4	Toxic for reproduction
Strontium chromate		232-142-6	7789-06-2	Carcinogenic
Sulfurous acid, lead salt, dibasic		263-467-1	62229-08-7	Toxic for reproduction
Tetraboron disodium heptaoxide, hydrate		235-541-3	12267-73-1	Toxic for reproduction
Tetraethyllead		201-075-4	78-00-2	Toxic for reproduction

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list
Tetralead trioxide sulphate		235-380-9	12202-17-4	Toxic for reproduction
Trichloroethylene		201-167-4	79-01-6	Carcinogenic
Tricosafluorododecanoic acid		206-203-2	307-55-1	vPvB
Triethyl arsenate		427-700-2	15606-95-8	Carcinogenic
Trilead bis(carbonate)dihydroxide		215-290-6	1319-46-6	Toxic for reproduction
Trilead diarsenate		222-979-5	3687-31-8	Carcinogenic and toxic for reproduction
Trilead dioxide phosphonate		235-252-2	12141-20-7	Toxic for reproduction
Tris(2-chloroethyl)phosphate		204-118-5	115-96-8	Toxic for reproduction
Trixylyl phosphate		246-677-8	25155-23-1	Toxic for reproduction
Zirconia Aluminosilicate Refractory Ceramic Fibres	are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions: a) Al2O3, SiO2 and ZrO2 are present within the following concentration ranges: Al2O3: 35–36 % w/w, and SiO2: 47.5–50 % w/w, and ZrO2: 15–17 % w/w, b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (μm).	–	Extracted from Index no. 650-017-00-8	Carcinogenic
α,α-Bis[4-(dimethylamino)phenyl]-4-(phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4)	with ≥ 0.1 % of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)	229-851-8	6786-83-0	Carcinogenic

Name of substance	Additional information on the substance	EC No	CAS No	Reason for inclusion on list

[*] The EC number includes both anhydrous and hydrated forms of a substance and consequently the entries cover both these forms. The CAS number included may be for the anhydrous form only, and therefore the CAS number shown does not always describe the entry accurately.

[1] The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5)

[2] The substance does not meet the criteria for identification as a carcinogen in situations where it contains less than 0.005 % (w/w) benzo[a]pyrene (EINECS No 200-028-5) and less than 0.1 % w/w benzene (EINECS No 200-753-7).]